ENVIRONMENTAL PROTECTION AGENCY

[FRL–5605–9]

Proposed Guidelines for Ecological Risk Assessment

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of Availability and Opportunity to Comment on Proposed Guidelines for Ecological Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today publishing a document entitled Proposed Guidelines for Ecological Risk Assessment (hereafter ''Proposed Guidelines''). These Proposed Guidelines were developed as part of an interoffice Guidelines development program by a Technical Panel of the Risk Assessment Forum. The Proposed Guidelines expand upon the previously published EPA report Framework for Ecological Risk Assessment (EPA/630/R–92/001, February 1992), while retaining the report's broad scope. When final, these Proposed Guidelines will help improve the quality of ecological risk assessments at EPA while increasing the consistency of assessments among the Agency's program offices and regions.

DATES: The Proposed Guidelines are being made available for a 90-day public review and comment period. Comments must be in writing and must be postmarked by December 9, 1996. See Addresses section for guidance on submitting comments.

FOR FURTHER INFORMATION CONTACT: Bill van der Schalie, National Center for Environmental Assessment-Washington Office, telephone: 202–260–4191.

ADDRESSES: The Proposed Guidelines will be made available in the following ways:

(1) The electronic version will be accessible on EPA's Office of Research and Development home page on the Internet at http://www.epa.gov/ORD/WebPubs/fedreg.

(2) 3½″ high-density computer diskettes in Wordperfect 5.1 format will be available from ORD Publications, Technology Transfer and Support Division, National Risk Management Research Laboratory, Cincinnati, OH; telephone: 513–569–7562; fax: 513–569–7566. Please provide the EPA No. (EPA/630/R–95/002B) when ordering.

(3) This notice contains the full proposed guideline. In addition, copies will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program, and for purchase from the National Technical Information Service (NTIS), Springfield, VA; telephone: 703–487–4650, fax: 703–321–8547. Please provide the NTIS No. PB96–193198; Price Code A13: ($47.00) when ordering.

Submitting Comments

Comments on the Proposed Guidelines should be submitted to: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), Attn: File ORD–ERA–96–01, Waterside Mall, 401 M St. SW, Washington, DC 20460. Please submit one unbound original with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively, provide comment on how the attachments relate to the main comment(s), and submit an unbound original and three copies. Please identify all comments and attachments with the file number ORD–ERA–96–01. Mailed comments must be postmarked by the date indicated. Comments may also be submitted electronically by sending electronic mail (e-mail) to: A-and-R-Docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments in electronic form also must be identified by the file number ORD–ERA–96–01.

The Air and Radiation Docket and Information Center is open for public inspection and copying between 8:00 a.m. and 5:30 p.m., weekdays, in Room M–1500, Waterside Mall, 401 M St. SW, Washington, DC 20460. The Center is located on the ground floor in the commercial area of Waterside Mall. The file index, materials, and comments are available for review in the information center or copies may be mailed on request from the Air and Radiation Docket and Information Center by calling (202) 260–7548 or –7549. The FAX number for the Center is (202) 260–4400. A reasonable fee may be charged for copying materials.

Please note that all technical comments received in response to this notice will be placed in the public record. For that reason, commentors should not submit personal information such as medical data or home addresses, confidential business information, or information protected by copyright. Due to limited resources, acknowledgments will not be sent.

SUPPLEMENTARY INFORMATION: These Proposed Guidelines are EPA's first Agency-wide ecological risk assessment guidelines. They are broad in scope, describing general principles and providing numerous examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological/spatial/temporal scales. This general approach provides sufficient flexibility to permit EPA's offices and regions to develop specific guidance suited to their particular needs. Because of their broad scope, the Proposed Guidelines do not provide detailed guidance in specific areas nor are they highly prescriptive. Frequently, rather than requiring that certain procedures always be followed, the Proposed Guidelines describe the strengths and limitations of alternate approaches. Agency preferences are expressed where possible, but because ecological risk assessment is a relatively new, rapidly evolving discipline, requirements for specific approaches could soon become outdated. EPA is working to expand the references in the Proposed Guidelines to include additional review articles or key publications that will help provide a ''window to the literature'' as recommended by peer reviewers. In the future, EPA intends to develop a series of shorter, more detailed guidance documents on specific ecological risk assessment topics after these Proposed Guidelines have been finalized.

These Proposed Guidelines were prepared during a time of increasing interest in the field of ecological risk assessment and reflect input from many sources outside as well as inside the Agency. Over the last few years, the National Research Council proposed an ecological risk paradigm (NRC, 1993), there has been a marked increase in discussion of ecological risk assessment issues at meetings of professional organizations, and numerous articles and books on the subject have been published. Agency work on the Proposed Guidelines has proceeded in a step-wise fashion during this time. Preliminary work began in 1989 and included a series of colloquia sponsored by EPA's Risk Assessment Forum to identify and discuss significant issues in ecological risk assessment (U.S. EPA, 1991). Based on this early work and on a consultation with EPA's Science Advisory Board (SAB), the Agency decided to produce ecological risk assessment guidance sequentially, beginning with basic terms and concepts and continuing with the development of source materials for these Proposed Guidelines. The first product of this effort was the Risk Assessment Forum report, Framework for Ecological Risk Assessment (Framework Report; U.S. EPA, 1992a,b), which proposes principles and terminology for the ecological risk assessment process. Since then, the Agency has solicited suggestions for ecological risk assessment guidelines structuring (U.S. EPA, 1992c) and has sponsored the development of other peer-reviewed materials, including ecological assessment case studies (U.S. EPA, 1993a, 1994a), and a set of issue papers that highlight important principles and approaches that EPA scientists should consider in preparing these Proposed Guidelines (U.S. EPA, 1994b,c).

The nature and content of these Proposed Guidelines have been shaped by these documents as well as numerous meetings and discussions with individuals both within and outside of EPA. In late 1994 and early 1995, the Agency solicited responses to the planned nature and structure of these Proposed Guidelines at three colloquia with Agency program offices and regions, other Federal agencies, and the public. Draft Proposed Guidelines were discussed at an external peer review workshop in December, 1995 (U.S. EPA, In Press). Subsequent reviews have included the Agency's Risk Assessment Forum and the Regulatory and Policy Development Committee, and interagency comment by members of subcommittees of the Committee on the Environment and Natural Resources of the Office of Science and Technology Policy. The EPA appreciates the efforts of all participants in the process and has tried to address their recommendations in these Proposed Guidelines.

The EPA's Science Advisory Board will review these Proposed Guidelines at a future meeting. Following public and SAB reviews, Agency staff will prepare comment summaries. Appropriate comments will be incorporated, and the revised Guidelines will be submitted to EPA's Risk Assessment Forum for review. The Agency will consider comments from the public, the SAB, and the Risk Assessment Forum when finalizing these Proposed Guidelines.

The public is invited to provide comments to be considered in EPA decisions about the content of the final Guidelines. EPA asks those who respond to this notice to include their views on the following:

(1) Consistent with a recent National Research Council report (NRC, 1996), these Proposed Guidelines emphasize the importance of interactions between risk assessors and risk managers as well as the critical role of problem formulation to ensuring that the results of the risk assessment can be used for decision-making. Overall, how compatible are these Proposed Guidelines with the National Research Council concept of the risk assessment process and the interactions between risk assessors, risk managers, and other interested parties?

(2) The Proposed Guidelines are intended to provide a starting point for Agency program and regional offices that wish to prepare ecological risk assessment guidance suited to their needs. In addition, the Agency intends to sponsor development of more detailed guidance on certain ecological risk assessment topics. Examples might include identification and selection of assessment endpoints, selection of surrogate or indicator species, or the development and application of uncertainty factors. Considering the state of the science of ecological risk assessment and Agency needs and priorities, what topics most require additional guidance?

(3) Some reviewers have suggested that the Proposed Guidelines should provide more discussion of topics related to the use of field observational data in ecological risk assessments, such as selection of reference sites, interpretation of positive and negative field data, establishing causal linkages, identifying measures of ecological condition, the role and uses of monitoring, and resolving conflicting lines of evidence between field and laboratory data. Given the general scope of these Proposed Guidelines, what, if any, additional material should be added on these topics and, if so, what principles should be highlighted?

(4) The scope of the Proposed Guidelines is intentionally broad. However, while the intent is to cover the full range of stressors, ecosystem types, levels of biological organization, and spatial/temporal scales, the contents of the Proposed Guidelines are limited by the present state of the science and the relative lack of experience in applying risk assessment principles to some areas. In particular, given the Agency's present interest in evaluating risks at larger spatial scales, how could the principles of landscape ecology be more fully incorporated into the Proposed Guidelines?

(5) Assessing risks when multiple stressors are present is a challenging task. The problem may be how to aggregate risks attributable to individual stressors or to identify the principal stressors responsible for an observed effect. Although some approaches for evaluating risks associated with chemical mixtures are available, our ability to conduct risk assessments involving multiple chemical, physical, and biological stressors, especially at larger spatial scales, is limited. Consequently, the Proposed Guidelines primarily discuss predicting the effects of chemical mixtures and on general approaches for evaluating causality of an observed effect. What additional principles can be added?

(6) Ecological risk assessments are frequently conducted in tiers that proceed from simple evaluations of exposure and effects to more complex assessments. While the Proposed Guidelines acknowledge the importance of tiered assessments, the wide range of applications of tiered assessments make further generalizations difficult. Given the broad scope of the Proposed Guidelines, what additional principles for conducting tiered assessments can be discussed?

(7) Assessment endpoints are ''explicit expression of the environmental value that is to be protected''. As used in the Proposed Guidelines, assessment endpoints include both an ecological entity and a specific attributes of the entity (e.g., eagle reproduction or extent of wetlands). Some reviewers have recommended that assessment endpoints also include a decision criterion that is defined early in the risk assessment process (e.g., no more than a 20% reduction in reproduction, no more than a 10% loss of wetlands). While not precluding this possibility, the Proposed Guidelines suggest that such decisions are more appropriately made during discussions between risk assessors and managers in risk characterization at the end of the process. What are the relative merits of each approach?

Dated: August 21, 1996.

Carol M. Browner,

Administrator.

Proposed Guidelines for Ecological Risk Assessment

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Executive Summary

The ecological problems facing environmental scientists and decisionmakers are numerous and varied. Growing concern over potential global climate change, loss of biodiversity, acid precipitation, habitat destruction, and the effects of multiple chemicals on ecological systems has highlighted the need for flexible problem-solving approaches that can link ecological measurements and data with the decisionmaking needs of environmental managers. Increasingly, ecological risk assessment is being suggested as a way to address this wide array of ecological problems.

Ecological risk assessment ''evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors'' (U.S. EPA, 1992a). It is a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. Ecological risk assessment provides a critical element for environmental decisionmaking by giving risk managers an approach for considering available scientific information along with the other factors they need to consider (e.g., social, legal, political, or economic) in selecting a course of action.

To help improve the quality and consistency of EPA's ecological risk assessments, EPA's Risk Assessment Forum initiated development of these guidelines. The primary audience for this document is risk assessors and risk managers at EPA, although these guidelines may be useful to others outside the Agency (e.g., Agency contractors, state agencies, and other interested parties). These guidelines are based on and replace the 1992 report, Framework for Ecological Risk Assessment (referred to as the Framework Report). They were written by a Forum work group and have been extensively revised based on comments from outside peer reviewers as well as Agency staff. The guidelines retain the Framework Report's broad scope, while expanding on some framework concepts and modifying others to reflect Agency experiences. EPA intends to follow these guidelines with a series of shorter, more detailed documents that address specific ecological risk assessment topics. This ''bookshelf'' approach provides the flexibility necessary to keep pace with developments in the rapidly evolving field of ecological risk assessment while allowing time to form consensus, where appropriate, on science policy inferences (default assumptions) to bridge gaps in knowledge.

Ecological risk assessment includes three primary phases (problem formulation, analysis, and risk characterization). Within problem formulation, important areas include identifying goals and assessment endpoints, preparing the conceptual model, and developing an analysis plan. The analysis phase involves evaluating exposure to stressors and the relationship between stressor levels and ecological effects. In risk characterization, key elements are estimating risk through integration of exposure and stressor-response profiles, describing risk by discussing lines of evidence and determining ecological adversity, and preparing a report. The interface between risk assessors and risk managers at the beginning and end of the risk assessment is critical for ensuring that the results of the assessment can be used to support a management decision.

Both risk assessors and risk managers bring valuable perspectives to the initial planning activities for an ecological risk assessment. Risk managers charged with protecting environmental values can ensure that the risk assessment will provide information relevant to a decision. Ecological risk assessors ensure that science is effectively used to address ecological concerns. Both evaluate the potential value of conducting a risk assessment to address identified problems. Further objectives of the initial planning process are to establish management goals that are agreed upon, clearly articulated, and contain a way to measure success; determine the purpose for the risk assessment by defining the decisions to be made within the context of the management goals; and agree upon the scope, complexity, and focus of the risk assessment, including the expected output and available resources.

Problem formulation, which follows these planning discussions, provides a foundation upon which the entire risk assessment depends. Successful completion of problem formulation depends on the quality of three products: assessment endpoints, conceptual models, and an analysis plan. Since problem formulation is inherently interactive and iterative, not linear, substantial reevaluation is expected to occur within and among all products of problem formulation.

Assessment endpoints are ''explicit expressions of the actual environmental value that is to be protected'' (U.S. EPA, 1992a) that link the risk assessment to management concerns. Assessment endpoints include both a valued ecological entity and an attribute of that entity that is important to protect and potentially at risk (e.g., nesting and feeding success of piping plovers or areal extent and patch size of eelgrass). For a risk assessment to have scientific validity, assessment endpoints must be ecologically relevant to the ecosystem they represent and susceptible to the stressors of concern. Assessment endpoints that represent societal values and management goals are more effective in that they increase the likelihood that the risk assessment will be used in management decisions. Assessment endpoints that fulfill all three criteria provide the best foundation for an effective risk assessment.

Potential interactions between assessment endpoints and stressors are explored by developing a conceptual model. Conceptual models link anthropogenic activities with stressors and evaluate interrelationships between exposure pathways, ecological effects, and ecological receptors. Conceptual models include two principal components: risk hypotheses and a conceptual model diagram.

Risk hypotheses describe predicted relationships between stressor, exposure, and assessment endpoint response. Risk hypotheses are hypotheses in the broad scientific sense; they do not necessarily involve statistical testing of null and alternative hypotheses or any particular analytical approach. Risk hypotheses may predict the effects of a stressor (e.g., a chemical release) or they may postulate what stressors may have caused observed ecological effects. Key risk hypotheses are identified for subsequent evaluation in the risk assessment.

A useful way to express the relationships described by the risk hypotheses is through a diagram of a conceptual model. Conceptual model diagrams are useful tools for communicating important pathways in a clear and concise way and for identifying major sources of uncertainty. Risk assessors can use these diagrams and risk hypotheses to identify the most important pathways and relationships that will be evaluated in the analysis phase. Risk assessors justify what will be done as well as what will not be done in the assessment in an analysis plan.

The analysis plan also describes the data and measures to be used in the risk assessment and how risks will be characterized.

The analysis phase, which follows problem formulation, includes two principal activities: characterization of exposure and characterization of ecological effects. The process is flexible, and interaction between the ecological effects and exposure evaluations is recommended. Both activities include an evaluation of available data for scientific credibility and relevance to assessment endpoints and the conceptual model. In exposure characterization, data analyses describe the source(s) of stressors, the distribution of stressors in the environment, and the contact or co-occurrence of stressors with ecological receptors. In ecological effects characterization, data analyses may evaluate stressor-response relationships or evidence that exposure to a stressor causes an observed response.

The products of analysis are summary profiles that describe exposure and the stressor-response relationships. Exposure and stressor-response profiles may be written documents or modules of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated.

The exposure profile identifies receptors and exposure pathways and describes the intensity and spatial and temporal extent of exposure. The exposure profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur.

The stressor-response profile may evaluate single species, populations, general trophic levels, communities, ecosystems, or landscapes—whatever is appropriate for the assessment endpoints. For example, if a single species is affected, effects should represent appropriate parameters such as effects on mortality, growth, and reproduction, while at the community level, effects may be summarized in terms of structure or function depending on the assessment endpoint. The stressor-response profile summarizes the nature and intensity of effect(s), the time scale for recovery (where appropriate), causal information linking the stressor with observed effects, and uncertainties associated with the analysis.

Risk characterization is the final phase of an ecological risk assessment. During risk characterization, risks are estimated and interpreted and the strengths, limitations, assumptions, and major uncertainties are summarized. Risks are estimated by integrating exposure and stressor-response profiles using a wide range of techniques such as comparisons of point estimates or distributions of exposure and effects data, process models, or empirical approaches such as field observational data.

Risk assessors describe risks by evaluating the evidence supporting or refuting the risk estimate(s) and interpreting the adverse effects on the assessment endpoint. Criteria for evaluating adversity include the nature and intensity of effects, spatial and temporal scales, and the potential for recovery. Agreement among different lines of evidence of risk increases confidence in the conclusions of a risk assessment.

When risk characterization is complete, a report describing the risk assessment can be prepared. The report may be relatively brief or extensive depending on the nature and the resources available for the assessment and the information required to support a risk management decision. Report elements may include:

- A description of risk assessor/risk manager planning results.
- A review of the conceptual model and the assessment endpoints.
- A discussion of the major data sources and analytical procedures used.
- A review of the stressor-response and exposure profiles.
- A description of risks to the assessment endpoints, including risk estimates and adversity evaluations.
- A summary of major areas of uncertainty and the approaches used to address them.
- A discussion of science policy judgments or default assumptions used to bridge information gaps, and the basis for these assumptions.

To facilitate understanding, risk assessors should characterize risks ‘‘in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency’’ (U.S. EPA, 1995c).

After the risk assessment is completed, risk managers may consider whether additional follow-up activities are required. Depending on the importance of the assessment, confidence level in the assessment results, and available resources, it may be advisable to conduct another iteration of the risk assessment in order to facilitate a final management decision. Ecological risk assessments are frequently designed in sequential tiers that proceed from simple, relatively inexpensive evaluations to more costly and complex assessments. Initial tiers are based on conservative assumptions, such as maximum exposure and ecological sensitivity. When an early tier cannot sufficiently define risk to support a management decision, a higher assessment tier that may require either additional data or applying more refined analysis techniques to available data may be needed. Higher tiers provide more ecologically realistic assessments while making less conservative assumptions about exposure and effects.

Another option is to proceed with a management decision based on the risk assessment and develop a monitoring plan to evaluate the results of the decision. For example, if the decision was to mitigate risks through exposure reduction, monitoring could help determine whether the desired reduction in exposure (and effects) was achieved. Monitoring is also critical for determining the extent and nature of any ecological recovery that may be occurring. Experience obtained by using focused monitoring results to evaluate risk assessment predictions can help improve the risk assessment process and is encouraged.

Communicating ecological risks to the public is usually the responsibility of risk managers. Although the final risk assessment document (including its risk characterization sections) can be made available to the public, the risk communication process is best served by tailoring information to a particular audience. It is important to clearly describe the ecological resources at risk, their value, and the costs of protecting (and failing to protect) the resources (U.S. EPA, 1995c). The degree of confidence in the risk assessment and the rationale for risk management decisions and options for reducing risk are also important (U.S. EPA, 1995c).

1. Introduction

Ecological risk assessment is a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. Ecological risk assessment provides a critical element for environmental decisionmaking. This document, which is structured by the stages of the ecological risk assessment process, provides Agency personnel with broad guidelines that can be adapted to their specific requirements.

The full definition of ecological risk assessment is:

''The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.'' (U.S. EPA, 1992a)

Several terms within this definition require further explanation:

• ''* * * likelihood * * *'' Descriptions of risk may range from qualitative judgments to quantitative probabilities. While risk assessments may include quantitative risk estimates, the present state of the science often may not support such quantitation. It is preferable to convey qualitatively the relative magnitude of uncertainties to a decision maker than to ignore them because they may not be easily understood or estimated.

• ''* * * adverse ecological effects * * *'' Ecological risk assessments deal with anthropogenic changes that are considered undesirable because they alter valued structural or functional characteristics of ecological systems. An evaluation of adversity may consider the type, intensity, and scale of the effect as well as the potential for recovery.

• ''* * * may occur or are occurring * * *'' Ecological risk assessments may be prospective or retrospective. Retrospective ecological risk assessments evaluate the likelihood that observed ecological effects are associated with previous or current exposures to stressors. Many of the same methods and approaches are used for both prospective and retrospective assessments, and in the best case, even retrospective assessments contain predictive elements linking sources, stressors and effects.

• ''* * * one or more stressors * * *'' Ecological risk assessments may address single or multiple chemical, physical, or biological stressors. (See Appendix A for definitions of stressor types.) Because risk assessments are conducted to provide input to management decisions, this document focuses on stressors generated or influenced by anthropogenic activity.

The overall ecological risk assessment process is shown in figure 1–1.[1] Problem formulation is the first phase of the process where the assessment purpose is stated, the problem defined, and the plan for analyzing and characterizing risk determined. In the analysis phase, data on potential effects of and exposures to stressor(s) identified during problem formulation are technically evaluated and summarized as exposure and stressor-response profiles. These profiles are integrated in risk characterization to estimate the likelihood of adverse ecological effects. Major uncertainties, assumptions, and strengths and limitations of the assessment are summarized during this phase. While discussions between risk assessors and risk managers are emphasized both at risk assessment initiation (planning) and completion (communicating results), these guidelines maintain a distinction between risk assessment and risk management. Risk assessment focuses on evaluating the likelihood of adverse effects, and risk management involves the selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results. Section 1.1 briefly discusses how risk assessments fit into a decisionmaking context.

[1] Changes in process and terminology from EPA's previous ecological risk assessment framework (U.S. EPA, 1992a) are summarized in Appendix A.

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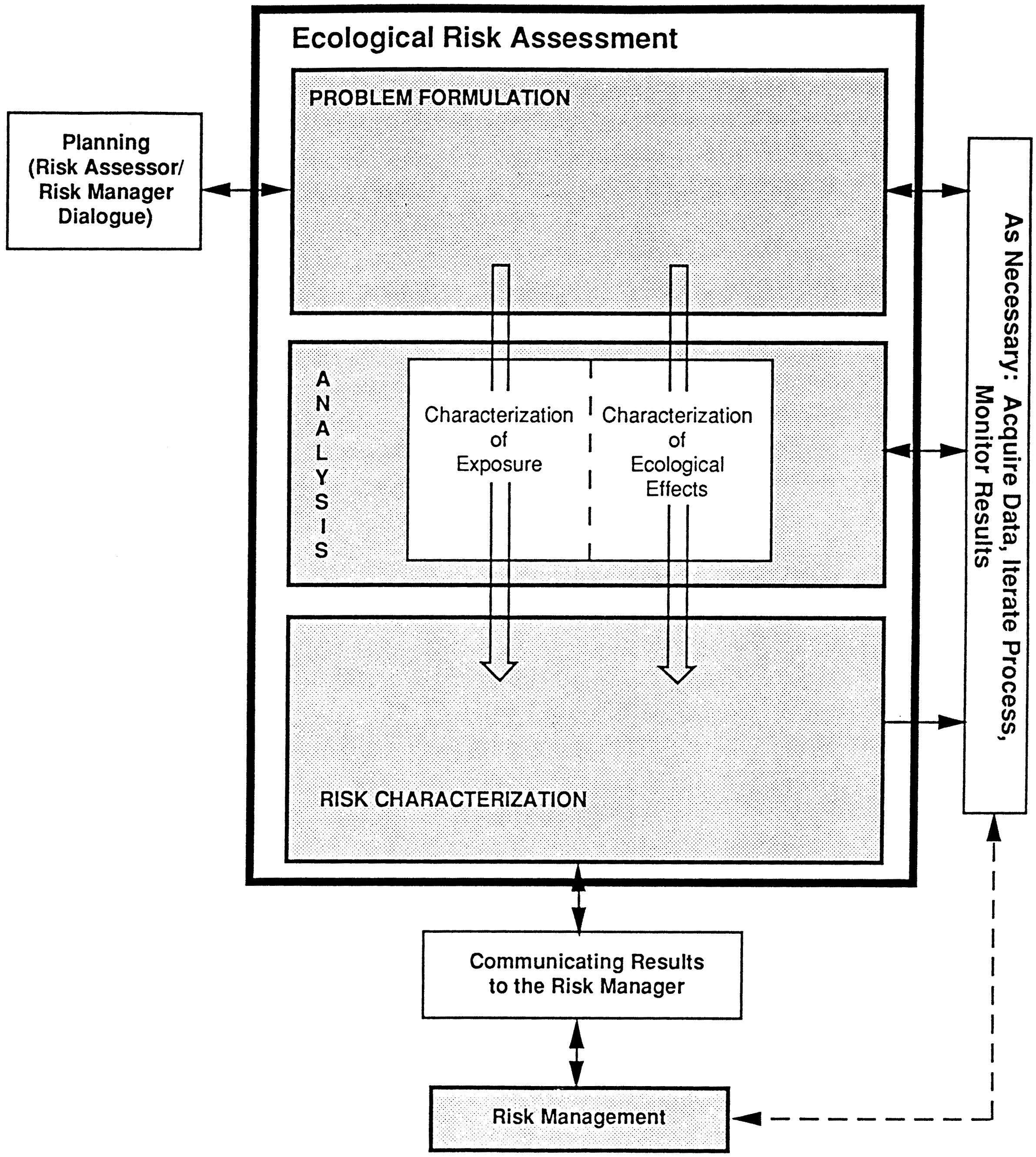

Figure 1-1. The framework for ecological risk assessment (U.S. EPA, 1992a). Ecological risk assessment is shown as a three-phase process including problem formulation, analysis, and risk characterization. Important activities associated with ecological risk assessment include discussions between risk assessors and risk managers and data acquisition and monitoring. Ecological risk assessments frequently follow an iterative or tiered approach.

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The bar along the right side of figure 1–1 shows several activities that are associated with risk assessments: data acquisition, iteration, and monitoring. While the risk assessment may focus on data analysis and interpretation, acquiring the appropriate quantity and quality of data for use in the process is critical. If such data are lacking, the risk assessment may stop until the necessary data are acquired. As discussed in text note 1–3, the process is more frequently iterative than linear, since the evaluation of new data or information may require revisiting a part of the process or conducting a new assessment.

Monitoring data can provide important input to all phases of the risk assessment process. For example, monitoring can provide the impetus for initiating a risk assessment by identifying changes in ecological condition. In addition, monitoring data can be used to evaluate the results predicted by the risk assessment. For example, follow-up studies could be used to determine whether techniques used to mitigate pesticide exposures in field situations in fact reduce exposure and effects as predicted by the risk assessment. Or, for a hazardous waste site, monitoring might help verify whether source reduction resulted in anticipated ecological changes. Monitoring is also critical for determining the extent and nature of any ecological recovery that may occur. The experience gained by comparing monitoring results to evaluate risk assessment predictions can help improve the risk assessment process and is encouraged.

1.1. Ecological Risk Assessment in a Management Context

Ecological risk assessment is important for environmental decisionmaking because of the high cost of eliminating environmental risks associated with human activities and the necessity of making regulatory decisions in the face of uncertainty (Ruckelshaus, 1983; Suter, 1993a). Even so, ecological risk assessment provides only a portion of the information required to make risk management decisions. This section describes how ecological risk assessments fit into a larger management framework.

1.1.1. Contributions of Ecological Risk Assessment to Environmental Decisionmaking

At EPA, ecological risk assessments provide input to a diverse set of environmental decisionmaking processes, such as the regulation of hazardous waste sites, industrial chemicals, and pesticides, or the management of watersheds affected by multiple nonchemical and chemical stressors. The ecological risk assessment process has several features that contribute to managing ecological risks:

• In a risk assessment, changes in ecological effects can be expressed as a function of changes in exposure to a stressor. This inherently predictive aspect of risk assessment may be particularly useful to the decision maker who must evaluate tradeoffs and examine different alternatives.

• Risk assessments include an explicit evaluation of uncertainties. Uncertainty analysis lends credibility and a degree of confidence to the assessment that can strengthen its use in decisionmaking and can help the risk manager focus research on those areas that will lead to the greatest reductions in uncertainty.

• Risk assessments can provide a basis for comparing, ranking, and prioritizing risks. The risk manager can use such information to help decide among several management alternatives.

• Risk assessments emphasize consistent use of well-defined and relevant endpoints. This is especially important for ensuring that the results of the risk assessment will be expressed in a way that the risk manager can use.

1.1.2. Risk Management Considerations

Although risk assessors and risk managers interact both at the initiation and completion of an ecological risk assessment (sections 2, 3, 5 and 6), risk managers decide how to use the results of an assessment and whether a risk assessment should be conducted. While a detailed review of management issues is beyond the scope of these guidelines, key areas are highlighted below.

• A risk assessment is not always required for management action. When faced with compelling ecological risks and an immediate need to make a decision, a risk manager might proceed without an assessment, depending on professional judgment and statutory requirements (U.S. EPA, 1992a).

• Because initial management decisions or statutory requirements significantly affect the scope of an assessment, it is important, where possible, for risk managers to consider a broader scope or alternative actions for a risk assessment. Sometimes a particular statute may require the risk assessment to focus on one type of stressor (e.g., chemicals) when there are other, perhaps more important, stressors in the system (e.g., habitat alteration). In other situations, however, it may be possible to evaluate a range of options. For example, before requesting an ecological risk assessment of alternative sites for the construction and operation of a dam for hydroelectric power, risk managers may consider larger issues such as the need for the additional power and the feasibility of using other power-generating options.

• Risk managers consider many factors in making regulatory decisions. Legal mandates may require the risk manager to take certain courses of action. Political and social considerations may lead the risk manager to make decisions that are either more or less ecologically protective. Economic factors may also be critical. For example, a course of action that has the least ecological risk may be too expensive or technologically infeasible. If cost-benefit analysis is applied, ecological risks may be translated into monetary terms to be compared against other monetary considerations. Thus, while ecological risk assessment provides critical information to risk managers, it is only part of the whole environmental decisionmaking process.

1.2. Scope and Intended Audience

These guidelines replace the EPA report, Framework for Ecological Risk Assessment (referred to as the Framework Report, U.S. EPA, 1992a). As a next step in developing Agency-wide guidance, the guidelines expand on and modify framework concepts to reflect Agency experience in the several years since the Framework Report was published (see Appendix A). Like the Framework Report, these guidelines are broad in scope, describing general principles and providing numerous examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological, spatial, and temporal scales. This approach provides flexibility to permit EPA's offices and regions to develop specific guidance suited to their particular needs.

The proposed policies set out in this document are intended as internal guidance for EPA. Risk assessors and risk managers at EPA are the primary audience for this document, although these guidelines may be useful to others outside the Agency (e.g., Agency contractors, state agencies, and other interested parties). These Proposed Guidelines are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. This document is not a regulation and is not intended for EPA regulations. These Proposed Guidelines set forth current scientific thinking and approaches for conducting and evaluating ecological risk assessments. As with other EPA guidelines (developmental toxicity, 56 FR 63798–63826; exposure assessment, 57 FR 22888–22938; and carcinogenicity, 61 FR 17960–18011), EPA will revisit these guidelines as experience and scientific consensus evolves.

These guidelines do not provide detailed guidance in specific areas nor are they intended to be highly prescriptive. These guidelines describe the strengths and limitations of alternate approaches and may not apply to a particular situation based upon the circumstances. Agency preferences are expressed where possible, but because ecological risk assessment is a rapidly evolving discipline, requirements for specific approaches could soon become outdated. EPA intends to develop a series of shorter, more detailed guidance documents on specific ecological risk assessment topics after these guidelines have been finalized.

These guidelines emphasize processes and approaches for analyzing data rather than specific data collection techniques, methods, or models. Also, while these guidelines discuss the interface between the risk assessor and risk manager, a detailed discussion of the use of ecological risk assessment information in the risk management process (e.g., the economic, legal, political, or social implications of the risk assessment results) is beyond the scope of these guidelines. Other EPA publications discuss how ecological concerns have been addressed in decisionmaking at EPA (U.S. EPA, 1994g) and provide an introduction to ecological risk assessment for risk managers (U.S. EPA, 1995b).

1.3. Guidelines Organization

These guidelines are structured according to the ecological risk assessment process as shown in figure 1–2. Within problem formulation (section 3), important areas addressed include identifying goals and assessment endpoints, preparing the conceptual model, and developing an analysis plan. The analysis phase (section 4) involves evaluating exposure to stressors and the relationship between stressor levels and ecological effects. In risk characterization (section 5), key elements are estimating risk through integration of exposure and stressor-response profiles and describing risk by discussing lines of evidence, interpreting adversity, and summarizing uncertainty. In addition, discussions between the risk assessor and risk manager at the beginning (section 2) and end of the risk assessment (section 6) are highlighted.

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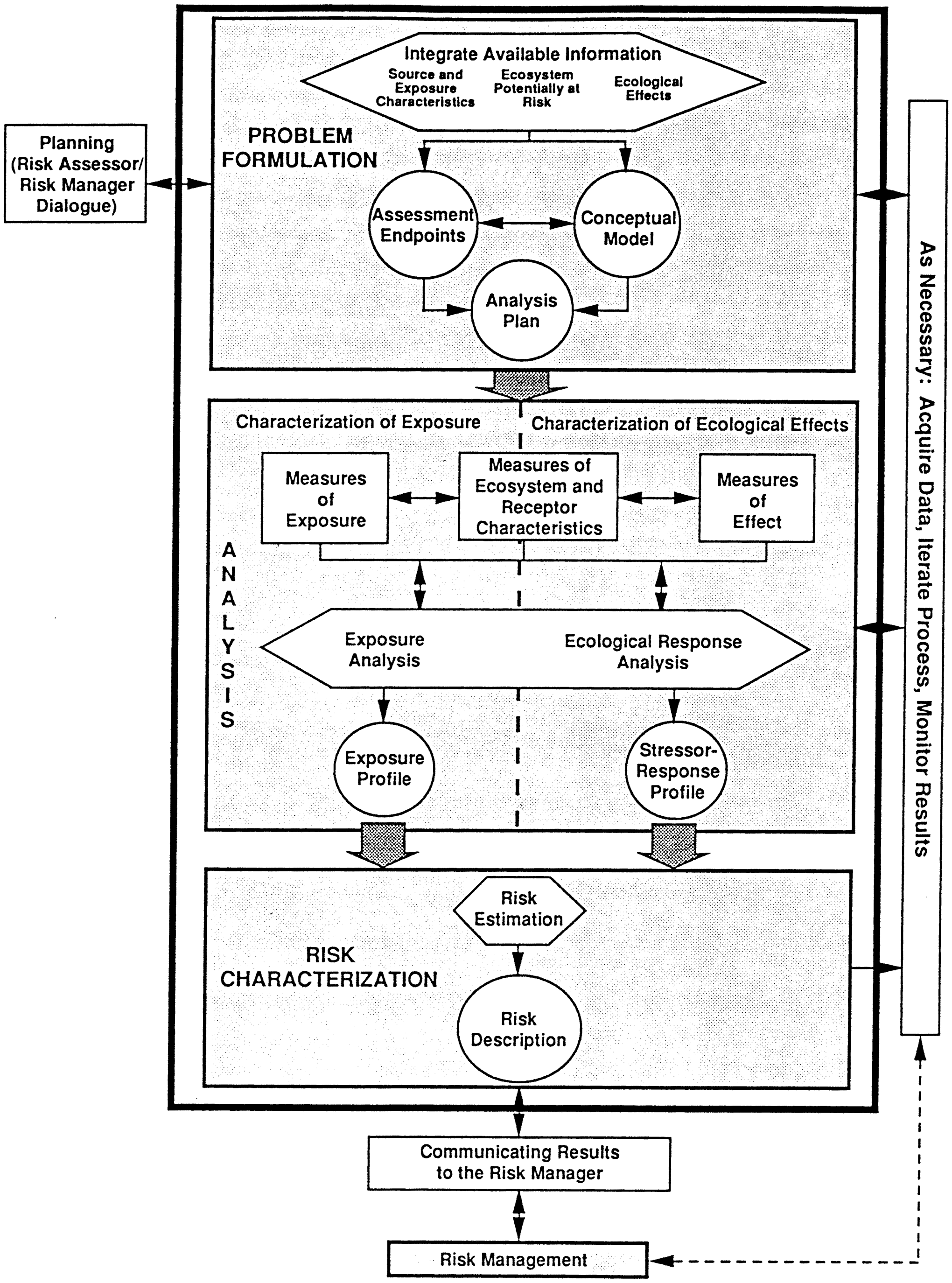

Figure 1-2. The ecological risk assessment framework, with an expanded view of each phase. Within each phase, rectangular boxes designate inputs, hexagon-shaped boxes indicate actions, and circular boxes represent outputs. Problem formulation, analysis, and risk characterization are discussed in sections 3, 4, and 5, respectively. Sections 2 and 6 describe interactions between risk assessors and risk managers.

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The reader may notice that cross-cutting topics are covered in several sections. These include uncertainty, models, evaluating data, causality, linking measures of effect to assessment endpoints, and identifying ecological effects. Considerations appropriate to the different phases of ecological risk assessment are discussed.

2. Planning The Risk Assessment: Dialogue Between Risk Managers and Risk Assessors

The purpose for an ecological risk assessment is to produce a scientific evaluation of ecological risk that enables managers to make informed environmental decisions. To ensure that ecological risk assessments meet risk managers' needs, a planning dialogue between risk managers and risk assessors (see text notes 2–1 and 2–2) is a critical first step toward initiating problem formulation and plays a continuing role during the conduct of the risk assessment. Planning is the beginning of a necessary interface between risk managers and risk assessors and is represented by a side box in the ecological risk assessment diagram (see figure 1–2). It is due to the importance of planning and the significant role it plays in ecological risk assessments that this section on planning is incorporated into guidelines on ecological risk assessment. However, it is imperative to remember that the planning process is distinct from the scientific conduct of an ecological risk assessment. This distinction helps ensure that political and social issues, while helping to define the objectives for the risk assessment, do not bias the scientific evaluation of risk.

During the planning dialogue, risk managers and risk assessors each bring important perspectives to the table. In general, risk managers are charged with protecting societal values (e.g., human health and the environment) and must ensure that the risk assessment will provide information relevant to a decision. To meet this charge, risk managers describe why the risk assessment is needed, what decisions it will support, and what they want to receive from the risk assessor. It is also helpful for managers to consider what problems they have encountered in the past when trying to use risk assessments for decisionmaking. In turn, it is the ecological risk assessors' role to ensure that science is effectively used to address ecological concerns. Risk assessors describe what they can provide to the risk manager, where problems are likely to occur, and where uncertainty may be problematic. Both evaluate the potential value of conducting a risk assessment to address identified problems.

Both risk managers and risk assessors are responsible for coming to agreement on the goals, scope, and timing of a risk assessment and the resources that are available and necessary to achieve the goals. Together they use information on the area's ecosystems, regulatory endpoints, and publicly perceived environmental values to interpret the goals for use in the ecological risk assessment. Examples of questions risk managers and risk assessors may address during planning are provided in text note 2–3.

The first step in planning may be to determine if a risk assessment is the best option for making the decision required. Questions concerning what is known about the degree of risk, what management options are available to mitigate or prevent it, and the value of conducting a risk assessment compared with other ways of learning about and addressing environmental concerns are asked during these discussions. In some cases, a risk assessment may add little value to the decision process. It is important for the risk manager and risk assessor to explore alternative options for addressing possible risk before continuing to the next planning stage (see section 1.1.2).

Once the decision is made to conduct a risk assessment, planning focuses on (1) establishing management goals that are agreed on, clearly articulated, and contain a way to measure success; (2) defining the decisions to be made within the context of the management goals; and (3) agreeing on the scope, complexity, and focus of the risk assessment, including the expected output and the technical and financial support available to complete it. To achieve these objectives, risk managers and risk assessors must each play an active role in planning the risk assessment.

2.1. Establishing Management Goals

Management goals for a risk assessment are established by risk managers but are derived in a variety of ways. Many Agency risk assessments are conducted based on legally established management goals (e.g., national regulatory programs generally have management goals written into the law governing the program). In this case, goal setting was previously completed through public debate in establishing the law. In most cases, legally established management goals do not provide sufficient guidance to the risk assessor. For example, the objectives under the Clean Water Act to ''protect and maintain the chemical, physical and biological integrity of the nation's waters'' are open to considerable interpretation. Agency managers and staff often interpret the law in regulations and guidance. Significant interaction between the risk assessor and risk manager may be needed to translate the law into management goals for a particular location or circumstance.

As the Agency increasingly emphasizes ''place-based'' or ''community-based'' management of ecological resources as recommended in the Edgewater Consensus (U.S. EPA, 1994e), management goals take on new significance for the ecological risk assessor. Management goals for ''places'' such as watersheds are formed as a consensus based on diverse values reflected in Federal, state, and local regulations; constituency group agendas; and public concerns. Significant interactions among a variety of interested parties are required to generate agreed-on management goals for the resource (see text note 2–4). Public meetings, constituency group meetings, evaluation of resource management organization charters, and other means of looking for management goals shared by these diverse groups may be necessary. Diverse risk management teams may elect to use social scientists trained in consensus-building methods to help establish management goals. While management goals derived in this way may require further definition (see text note 2–5), there is increased confidence that these goals are supported by the audience for the risk assessment.

Regardless of how management goals are established, goals that explicitly define which ecological values are to be protected are more easily used to design a risk assessment for decisionmaking than general management goals. Whenever goals are general, risk assessors must interpret those goals into ecological values that can be measured or estimated and ensure that the managers agree with their interpretation (see text note 2–6). Legally mandated goals generally are interpreted by Agency managers and staff. This interpretation may be performed once and then applied to the multiple similar assessments (e.g. evaluation of new chemicals). For other risk assessments, the interpretation is unique to the ecosystem being assessed and must be done on a case-by-case basis as part of the planning process.

2.2. Management Decisions

A risk assessment is shaped by the kind of decision it will support. When a management decision is explicitly stated and closely aligned to management actions, the scope, focus, and conduct of the risk assessment are well defined by the specificity of the decision to be made. Some of these risk assessments are used to help establish national policy that will be applied consistently across the country (e.g., premanufacture notices for new chemicals, protection of endangered species). Other risk assessments are designed for a specific site (e.g., hazardous waste site clean-up level). When decision options (e.g., decision criteria in the data quality objectives process, U.S. EPA, 1994d; see section 3.5.2 for more details) are known prior to the risk assessment, a number of assumptions are inherent in those options that need to be explicitly stated during planning. This ensures that the decision criteria are not altering the scientific validity of the risk assessment by inappropriately applying assumptions or unnecessarily limiting the variables. For many risk assessments, there may be a range of possible management options for managing risk. When different management options have been identified (e.g., leave alone, clean up, or pave a contaminated site), risk assessment can be used to predict potential risk across the range of these management options.

Risk assessments may be designed to provide guidance for management initiatives for a region or watershed where multiple stressors, ecological values, and political factors influence decisionmaking. These risk assessments require great flexibility and breadth and may use national risk-based information and site-specific risk information in conjunction with regional evaluations of risk. As risk assessment is more frequently used to support landscape-scale management decisions, the diversity, breadth, and complexity of the risk assessments increase significantly and may include evaluations that focus on understanding ecological processes influenced by a diversity of human actions and management options. Risk assessments used in this application are often based on a general goal statement and require significant planning to establish the purpose, scope, and complexity of the assessment.

2.3. Scope and Complexity of the Risk Assessment

Although the purpose for the risk assessment determines whether it is national, regional, or local, the resources available for conducting the risk assessment determines how extensive and complex it can be within this framework and the level of uncertainty that can be expected. Each risk assessment is constrained by the availability of data, scientific understanding, expertise, and financial resources. Within these constraints there is much to consider when designing a risk assessment. Risk managers and risk assessors must discuss in detail the nature of the decision (e.g., national policy, local economic impact), available resources, opportunities for increasing the resource base (e.g., partnering, new data collection, alternative analytical tools), and the output that will provide the best information for decisions required (see text note 2–7).

Part of the agreement on scope and complexity is based on the maximum uncertainty that is acceptable in whatever decision the risk assessment supports. The lower the tolerance for uncertainty, the greater the scope and complexity needed in the risk assessment. Risk assessments completed in response to legal mandates and likely to be challenged in court often require rigorous attention to acceptable levels of uncertainty to ensure that the assessment will be used in a decision. A frank discussion is needed between the risk manager and risk assessor on sources of uncertainty in the risk assessment and ways uncertainty can be reduced (if necessary) through selective investment of resources. Where appropriate, planning could account for the iterative nature of risk assessment and include explicitly defined steps. These steps may take the form of ''tiers'' that represent increasing levels of complexity and investment, with each tier designed to reduce uncertainty. The plan may include an explicit definition of iterative steps with a description of levels of investment and decision criteria for each tier. Guidance on addressing the interplay of management decisions, study boundaries, data needs, uncertainty, and specifying limits on decision errors may be found in EPA's guidance on data quality objectives (U.S. EPA, 1994d).

2.4. Planning Outcome

The planning phase is complete when agreements are reached on the management goals, assessment objectives, the focus and scope of the risk assessment, resource availability, and the type of decisions the risk assessment is to support. Agreements may encompass the technical approach to be taken in a risk assessment as determined by the regulatory or management context and reason for initiating the risk assessment (see section 3.2), the spatial scale (e.g., local, regional, or national), and temporal scale (e.g., the time frame over which stressors or effects will be evaluated).

In mandated risk assessments, planning agreements are often codified in regulations, and little documentation of agreements is warranted. In risk assessments where planning decisions can be highly variable, a summary of planning agreements may be important for ensuring that the risk assessment remains consistent with early agreements. A summary can provide a point of reference for determining if early decisions may need to be changed in response to new information. There is no defined format, length, or complexity for a planning summary. It is a useful reference only and should be tailored to the complexity of the risk assessment it represents. However, a summary is recommended to help ensure quality communication between and among risk managers and risk assessors and to document the decisions that have been agreed upon.

Once planning is complete, the formal process of risk assessment begins through the initiation of problem formulation. During problem formulation, risk assessors should continue the dialogue with risk managers following assessment endpoint selection and once the analysis plan is completed. At these points, potential problems can be identified before the risk assessment proceeds.

3. Problem Formulation Phase

Problem formulation is a formal process for generating and evaluating preliminary hypotheses about why ecological effects have occurred, or may occur, from human activities. As the first stage of an ecological risk assessment, it provides the foundation on which the entire assessment depends. During problem formulation, management goals developed during planning are evaluated to establish objectives for the risk assessment, the problem is defined, and the plan for analyzing data and characterizing risk is determined. Any deficiencies in problem formulation will compromise all subsequent work on the risk assessment (see text note 3–1).

3.1. Products of Problem Formulation

Successful completion of problem formulation depends on the quality of three products: (1) assessment endpoints that adequately reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor and assessment endpoint or among several stressors and assessment endpoints, and (3) an analysis plan. Essential to the development of these products are the effective integration and evaluation of available information.

The following discussion focuses on the products of problem formulation and the information that determines the nature of those products. The products are featured in the problem formulation diagram as circles (see figure 3–1). The types of information that must be evaluated to generate those products are shown in the hexagon.

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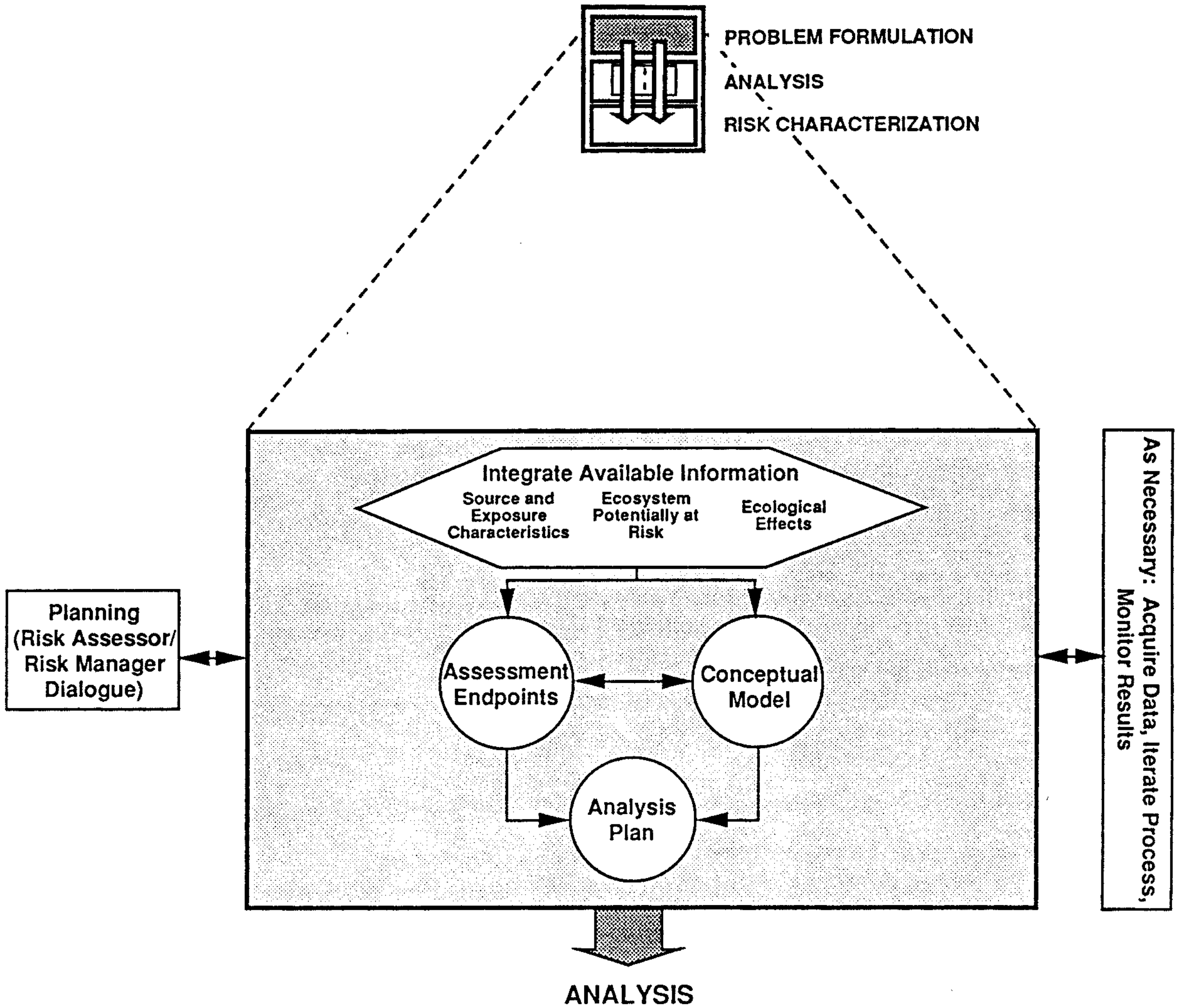

Figure 3-1. Problem formulation phase.

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To enhance clarity, the organization of the following discussion follows the above topics. However, problem formulation is not necessarily completed in the order presented here. First, the order in which products are produced is directly related to why the ecological risk assessment is initiated, as addressed in section 3.2. Second, problem formulation is inherently interactive and iterative, not linear. Substantial reevaluation is expected to occur within and among all products of problem formulation.

3.2. Integration of Available Information

The foundation for problem formulation is the integration of available information on the sources of stressors and stressor characteristics, exposure, the ecosystem(s) potentially at risk, and ecological effects (see figure 3–1). When key information is of the appropriate type and sufficient quality and quantity, problem formulation can proceed effectively. When key information is unavailable in one or more areas, the risk assessment may be temporarily suspended while new data are collected. If new data cannot be collected, then the risk assessment will depend on what is known and what can be extrapolated from that information. Complete information is not available at the beginning of many risk assessments. When this is the case, the process of problem formulation assists in identifying where key data are missing and provides the framework for further research where more data are needed. Where data are few, a clear articulation of the limitations of conclusions, or uncertainty, from the risk assessment becomes increasingly critical in risk characterization (see text note 3–2).

The reason why an ecological risk assessment is initiated directly influences what information is available at the outset, and what information must be found. A risk assessment can be initiated because a known or potential stressor may be released into the environment, an adverse effect or change in condition is observed, or better management of an important ecological value (e.g., valued ecological entities such as species, communities, ecosystems or places) is desired. Risk assessments are sometimes initiated for two or all three of these reasons.

Risk assessors beginning with information about the source or stressor will seek available information on the effects the stressor might be associated with and the ecosystems that it will likely be found in. Risk assessors beginning with information about an observed effect or change in condition will need to seek information about potential stressors and sources. Risk assessors starting with concern over a particular ecological value may need additional information on the specific condition or effect of interest, the ecosystems potentially at risk, and potential stressors and sources.

The initial use of available information is a scoping process similar to that used to develop environmental impact statements. During this process, data and information (i.e., actual, inferred, or estimated) are considered to ensure that nothing important is overlooked. A comprehensive evaluation of all information provides the framework for generating a large array of risk hypotheses to consider (see section 3.4.1). After the initial scoping process, information quality and applicability to the particular problem of concern are increasingly scrutinized as the risk assessor proceeds through problem formulation. When analysis plans are formed, data validity becomes a significant factor to consider. Issues relating to evaluating data quality are discussed in the analysis phase (see section 4.1).

As the complexity and spatial scale of a risk assessment increase, information needs escalate. Ecosystems characteristics directly influence when, how, and why particular ecological entities may become exposed and exhibit adverse effects due to particular stressors. Predicting risks from multiple chemical, physical, and biological stressors requires an understanding of their interactions. Risk assessments for a region or watershed, where multiple stressors are the rule, require consideration of ecological processes operating at larger spatial scales.

Despite limitations on what is known about ecosystems and the stressors influencing them, the process of problem formulation offers a valuable systematic approach for organizing and evaluating available information on all stressors and possible effects in a way that can be useful to risk assessors and decisionmakers. Text note 3–3 provides a series of questions that risk assessors should attempt to answer using available information, many of which were drawn from Barnthouse and Brown (1994). This exercise will help risk assessors identify known and unknown relationships, both of which are important in problem formulation.

Problem formulation proceeds with the identification of assessment endpoints, and the development of conceptual models and the analysis plan (discussed below). However, the order in which these task are done is influenced by the reason for initiating the assessment (text note 3–4). Early recognition that initiation effects the order of product generation will help facilitate the development of problem formulation.

3.3. Selecting Assessment Endpoints

Assessment endpoints are ‘‘explicit expressions of the actual environmental value that is to be protected’’ (U.S. EPA, 1992a). Assessment endpoints are critical to problem formulation because they link the risk assessment to management concerns and they are central to conceptual model development. Their relevance to ecological risk assessment is determined by how well they target susceptible ecological entities. Their ability to support risk management decisions depends on how well they represent measurable characteristics of the ecosystem that adequately represent management goals. The selection of ecological concerns and assessment endpoints in EPA has traditionally been done internally by individual Agency program offices (U.S. EPA, 1994g). More recently, Agency activities such as the watershed protection approach and community-based environmental protection have used contributions by interested parties in the selection of ecological concerns and assessment endpoints. This section describes criteria for selecting and defining assessment endpoints.

3.3.1. Selecting What To Protect

The ecological resources selected to represent management goals for environmental protection are reflected in the assessment endpoints that drive ecological risk assessments. Assessment endpoints often reflect environmental values that are protected by law, provide critical resources, or provide an ecological function that would be significantly impaired (or that society would perceive as having been impaired) if the resource were altered.

Although many potential assessment endpoints may be identified, considering the practicality of using particular assessment endpoints will help refine selections. For example, when the attributes of an assessment endpoint can be measured directly, extrapolation is unnecessary; therefore this uncertainty is not introduced into the results. Assessment endpoints that cannot be measured directly but can be represented by measures that are easily monitored and modeled still provide a good foundation for the risk assessment. Assessment endpoints that cannot be linked with measurable attributes are not appropriate for a risk assessment.

Three principal criteria are used when selecting assessment endpoints: (1) their ecological relevance, (2) their susceptibility to the known or potential stressors, and (3) whether they represent management goals. Of these three criteria, ecological relevance and susceptibility are essential for selecting assessment endpoints that are scientifically valid. Rigorous selection based on these criteria must be maintained. However, to increase the likelihood that the risk assessment will be used in management decisions, assessment endpoints that represent societal values and management goals are more effective. Given the complex functioning of ecosystems and the interdependence of ecological entities, it is likely that assessment endpoints can be selected that are responsive to management goals while meeting scientific criteria. This provides a way to address changes that may occur over time in the public's perception of ecological value (e.g., wetlands viewed as infested swamps 30 years ago are considered prime wildlife habitat today; Suter, 1993a). Assessment endpoints that meet all three criteria provide the best foundation for an effective risk assessment (e.g., see text note 3–5).

3.3.1.1. Ecological Relevance

Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints (U.S. EPA, 1992a). These are endpoints that help sustain the natural structure, function, and biodiversity of an ecosystem. For example, ecologically relevant endpoints may contribute to the food base (e.g., primary production), provide habitat, promote regeneration of critical resources (e.g., decomposition or nutrient cycling), or reflect the structure of the community, ecosystem, or landscape (e.g., species diversity or habitat mosaic). Changes in ecologically relevant endpoints can result in unpredictable and widespread effects.

Ecological relevance becomes most important when risk assessors are identifying the potential cascade of adverse effects that could result from the loss or reduction of one or more species or a change in ecosystem function (see text note 3–6). Careful selection of assessment endpoints that address both specific organisms of concern and landscape-level ecosystem processes becomes increasingly important in landscape-level risk assessments. In some cases, it may be possible to select one or more species and an ecosystem process to represent larger functional community or ecosystem processes.

Determining ecological relevance in specific cases requires expert judgment based on site-specific information, preliminary site surveys, or other available information. The less information available, the more critical it is to have informed expert judgment to ensure appropriate selections. If assessment endpoints in a risk assessment are not ecologically relevant, the results of the risk assessment may predict risk to the assessment endpoints selected but seriously misrepresent risk to the ecosystem of concern, which could lead to misguided management.

3.3.1.2. Susceptibility to Known or Potential Stressors

Ecological resources are considered susceptible when they are sensitive to a human-induced stressor to which they are exposed. Sensitivity refers to how readily an ecological entity is affected by a particular stressor. Sensitivity is directly related to the mode of action of the stressors. For example, chemical sensitivity is influenced by individual physiology and metabolic pathways. Sensitivity also is influenced by individual and community life-history characteristics. For example, species with long life cycles and low reproductive rates will be more vulnerable to extinction from increases in mortality than those with short life cycles and high reproductive rates. Species with large home ranges may be more sensitive to habitat fragmentation when the fragment is smaller than their required home range compared to those with smaller home ranges within a fragment. However, habitat fragmentation may also affect species with small home ranges where migration is a necessary part of their life history and fragmentation prevents exchange among subpopulations.

Sensitivity may be related to the life stage of an organism when exposed to a stressor. Frequently, young animals are more sensitive to stressors than adults. For example, Pacific salmon eggs and fry are very sensitive to sedimentation from forest logging practices and road building because they can be smothered. Age-dependent sensitivity, however, is not only in the young. In many species, special events like migration (e.g., in birds) and molting (e.g., in harbor seals) represent significant energy investments that make these organisms more vulnerable to an array of possible stressors. Finally, sensitivity may be increased by the presence of other stressors or natural disturbances. For example, the presence of insect pests and disease may make plants more sensitive to damage from ozone (Heck, 1993).

Measures of sensitivity may include mortality or adverse reproductive effects from exposure to toxics, behavioral abnormalities, avoidance of significant food sources or nesting sites, or loss of offspring to predation because of the proximity of stressors such as noise, habitat alteration or loss, community structural changes, or other factors.

Exposure is the other key determinant in susceptibility. Exposure can mean co-occurrence, contact, or the absence of contact, depending on the stressor and assessment endpoint (see section 4 for more discussion). The amount and conditions of exposure directly influence how an ecological entity will respond to a stressor. Thus, to determine what entities are susceptible, it is important to consider information on the proximity of an ecological resource to the stressor, the timing of exposure (both in terms of frequency and duration), and the intensity of exposure occurring during sensitive life stages of the organisms.

Adverse effects of a particular stressor may be important during one part of an organism's life cycle, such as early development or reproduction. Adverse effects may result from exposure to a stressor or to the absence of a necessary resource during a critical life stage. For example, if fish are unable to find suitable nesting sites during their reproductive phase, risk is significant even when water quality is high and food sources abundant. The interplay between life stage and stressors can be very complex (e.g., see text note 3–7).

Exposure may occur in one place or time, and effects may not occur until another place or time. Both life history characteristics, as described under sensitivity, and the circumstances of exposure, influence susceptibility in this case. For example, the temperature of the incubation medium of marine turtle eggs affects the sex ratio of the offspring. But the population impacts of a change in incubation temperature may not be observable until years later when the cohort of affected turtles begins to reproduce. Delayed effects and multiple stressor exposures add complexity to evaluations of susceptibility. For example, although toxicity tests may determine receptor sensitivity to one stressor, the degree of susceptibility may depend on the co-occurrence of another stressor that significantly alters receptor response. Conceptual models (see section 3.4) need to reflect these factors. If a species is unlikely to be exposed to the stressor of concern, it is inappropriate as an assessment endpoint.

3.3.1.3. Representation of Management Goals

Ultimately, the value of a risk assessment depends on whether it can support quality management decisions. Risk managers are more willing to use a risk assessment for making decisions when the assessment is based on values and organisms that people care about. These values, interpreted from management goals (see section 2) into assessment endpoints, provide a defined and measurable entity for the risk assessment. Candidates for assessment endpoints might include entities such as endangered species, commercially or recreationally important species, functional attributes that support food sources or flood control (wetland water sequestration, for example), or aesthetic values, such as clean air in national parks or the existence of charismatic species like eagles or whales.

Selection of assessment endpoints based on public perceptions alone could lead to management decisions that do not consider important ecological information. While being responsive to the public is important, it does not obviate the requirement for scientific validity as represented by the sections on ecological relevance and susceptibility. Many ecological entities and attributes meet the necessary scientific rigor as assessment endpoints; some will be recognized as valuable by risk managers and the public, and others will not. Midges, for example, can represent the base of a complex food web that supports a popular sports fishery. They may also be considered pests. While both midges and fish are important ecological entities in this ecosystem and represent key components of the aquatic community, selecting the fishery as the assessment endpoint and using midges as a critical ecological entity to measure allow both entities to be used in the risk assessment. This choice maintains the scientific validity of the risk assessment and is responsive to management concerns. In those cases where the risk assessor identifies a critical assessment endpoint that is unpopular with the public, the risk assessor may find it necessary to present a persuasive case in its favor based on scientific arguments.

3.3.2. Defining Assessment Endpoints

Assessment endpoints provide a transition between broad management goals and the specific measures used in an assessment. They help assessors identify measurable attributes to quantify and predict change. Assessment endpoints also help the risk assessor determine whether management goals have been or can be achieved (see text note 3–8).

Two elements are required to define an assessment endpoint. The first is the valued ecological entity. This can be a species (e.g., eelgrass, piping plover), a functional group of species (e.g., raptors), an ecosystem function or characteristic (e.g., nutrient cycling), a specific valued habitat (e.g., wet meadows) or a unique place (e.g., a remnant of native prairie). The second is the characteristic about the entity of concern that is important to protect and potentially at risk. For example, it is necessary to define what is important for piping plovers (e.g., nesting and feeding success), eelgrass (e.g., areal extent and patch size), and wetlands (e.g., endemic wet meadow community structure and function). For an assessment endpoint to provide a clear interpretation of the management goals and the basis for measurement in the risk assessment, both an entity and an attribute are required.

Assessment endpoints are distinct from management goals. They do not represent what the managers or risk assessors want to achieve. As such they do not contain words like ''protect,'' ''maintain,'' or ''restore,'' or indicate a direction for change such as ''loss'' or ''increase.''

Defining assessment endpoints can be difficult. They may be too broad, vague, or narrow, or they may be inappropriate for the ecosystem requiring protection. ''Ecological integrity'' is a frequently cited, but vague, goal and an even more vague assessment endpoint. ''Integrity'' can only be used effectively when its meaning is explicitly characterized for a particular ecosystem, habitat, or entity. This may be done by selecting key entities and processes of an ecosystem and describing characteristics that best represent integrity for that system. For example, general goals for Waquoit Bay were translated into several assessment endpoints, including ''estuarine eelgrass abundance and distribution'' (see text note 2–6).

Expert judgment and an understanding of the characteristics and function of an ecosystem are important for translating general goals into usable assessment endpoints. Endpoints that are too narrowly defined, however, may not support effective risk management. For example, if an assessment is focused on protecting the habitat of an endangered species, the risk assessment may overlook important characteristics of the ecosystem and fail to include critical variables (see text note 3–7).

Assessment endpoints must be appropriate for the ecosystem of concern. Selecting a game fish that grows well in reservoirs may meet a ''feasible'' management goal, but would be inappropriate for evaluating risk from a new hydroelectric dam if the ecosystem of concern is a stream in which salmon spawn (see text note 3–5). Although the game fish will satisfy the fishable goal and may be highly desired by local fishermen, a reservoir species does not represent the ecosystem at risk. A vague ''viable fish populations'' assessment endpoint substituted by ''reproducing populations of indigenous salmonids'' could therefore prevent the development of an inappropriate risk assessment.

Clearly defined assessment endpoints provide direction and boundaries for the risk assessment and can minimize miscommunication and reduce uncertainty. Assessment endpoints directly influence the type, characteristics, and interpretation of data and information used for analyses and the scale and character of the assessment. For example, an assessment endpoint such as ''egg production of pond invertebrates'' defines local population characteristics and requires very different types of data and ecosystem characterization compared with ''watershed aquatic community structure and function.'' If concerns are local, the assessment endpoints should not focus on landscape concerns. Where ecosystem processes and landscape mosaics are of concern, survival of a particular species would provide inadequate representation. Assessment endpoints that are poorly defined, inappropriate, or at the incorrect scale can be very problematic. Common problems encountered in selecting assessment endpoints are summarized in text note 3–9.

The presence of multiple stressors should influence the selection of assessment endpoints. When it is possible to select one assessment endpoint that is sensitive to many of the identified stressors, yet responds in different ways to different stressors, it is possible to consider the combined effects of multiple stressors while still discriminating among effects. For example, if recruitment of a fish population is the assessment endpoint, it is important to recognize that recruitment may be adversely affected at several life stages, in different habitats, through different ways, by different stressors. The measures of effect, exposure, and ecosystem and receptor characteristics chosen to evaluate recruitment provide a basis for discriminating among different stressors, individual effects, and their combined effect.

The assessment endpoint can provide a basis for comparing a range of stressors if carefully selected. For example, the National Crop Loss Assessment Network (Heck, 1993) selected crop yields as the assessment endpoint to evaluate the cumulative effects of multiple stressors. Although the primary stressor was ozone, the crop-yield endpoint allowed them to consider the effects of sulfur dioxide and soil moisture. As Barnthouse et al. (1990) pointed out, an endpoint should be selected so that all the effects can be expressed in the same units (e.g., the abundance of 1-year-old fish to assess the effects from toxicity, fishing pressure, and habitat loss). These considerations are important when selecting assessment endpoints for addressing the combined effect of multiple stressors. However, in situations where multiple stressors act on the structure and function of aquatic and terrestrial communities in a watershed ecosystem, an array of assessment endpoints that represent the ecosystem community and processes is more effective than a single endpoint. When based on differing susceptibility to an array of stressors, the careful selection of assessment endpoints can help risk assessors distinguish among effects from diverse stressors. Exposure to multiple stressors may lead to effects at different levels of biological organization, for a cascade of adverse responses that should be considered.

Although assessment endpoints must be defined in terms of measurable attributes, selection does not depend on the ability to measure those attributes directly or on whether methods, models, and data are currently available. If the response of an assessment endpoint cannot be directly measured, it may be predicted from responses of surrogate or similar entities. Although for practical reasons it is helpful to use assessment endpoints that have well-developed test methods, field measurement techniques, and predictive models (see Suter, 1993a), it is not necessary for these methods to be established protocols. Measures that will be used to evaluate assessment endpoint response to exposures for the risk assessment are often identified during conceptual model development and specified in the analysis plan. See section 3.5 for issues surrounding the selection of measures.

It is important for risk assessors and risk managers to agree that selected assessment endpoints represent the management goals for the particular ecological value. The rationale for their selection should be clear. Assessment endpoint selection is an important risk manager-risk assessor checkpoint during problem formulation.

3.4. Conceptual Models

A conceptual model in problem formulation is a written description and visual representation of predicted responses by ecological entities to stressors to which they are exposed, and the model includes ecosystem processes that influence these responses. Conceptual models represent many relationships (e.g., exposure scenarios may qualitatively link land-use activities to sources and their stressors, may describe primary, secondary, and tertiary exposure pathways, and may describe co-occurrence between exposure pathways, ecological effects, and ecological receptors).

Conceptual models for ecological risk assessments are developed from information about stressors, potential exposure, and predicted effects on an ecological entity (the assessment endpoint). Depending on why a risk assessment is initiated, one or more of these categories of information is known at the outset. The process of creating conceptual models helps identify the unknown elements.

The complexity of the conceptual model depends on the complexity of the problem, number of stressors, number of assessment endpoints, nature of effects, and characteristics of the ecosystem. For single stressors and single assessment endpoints, conceptual models can be relatively simple relationships. In situations where conceptual models describe both the pathways of individual stressors and assessment endpoints and the interaction of multiple and diverse stressors and assessment endpoints (e.g., assessments initiated because of important values), several submodels normally will be required to describe individual pathways. Other models may then be used to explore how these individual pathways interact.

Conceptual models consist of two principal products:

- A set of risk hypotheses that describe predicted relationships between stressor, exposure, and assessment endpoint response, along with the rationale for their selection.
- A diagram that illustrates the relationships presented in the risk hypotheses.

3.4.1. Risk Hypotheses

Hypotheses are assumptions made in order to evaluate logical or empirical consequences (Merriam-Webster, 1972). Risk hypotheses are statements of assumptions about risk based on available information (see text note 3–10). They are formulated using a combination of expert judgment and information on the ecosystem at risk, potential sources of stressors, stressor characteristics, and observed or predicted ecological effects on selected or potential assessment endpoints. These hypotheses may predict the effects of a stressor event before it happens, or they may postulate why observed ecological effects occurred and ultimately what sources and stressors caused the effect. Depending on the scope of the risk assessment, the set of risk hypotheses may be very simple, predicting the potential effect of one stressor on one receptor, or extremely complex, as is typical in value-initiated risk assessments that often include prospective and retrospective hypotheses about the effects of multiple complexes of stressors on diverse ecological receptors.

Although risk hypotheses should be developed even when information is incomplete, the amount and quality of data will affect the specificity and level of uncertainty associated with risk hypotheses and the conceptual models they form. When preliminary information is conflicting, risk hypotheses can be constructed specifically to differentiate among competing predictions. The predictions can then be evaluated systematically either by using available data during the analysis phase or by collecting new data before proceeding with the risk assessment. Hypotheses and predictions set a framework for using data to evaluate functional relationships (e.g., stressor-response curves).

Early conceptual models are intended to be broad in scope, identifying as many potential relationships as possible. As more information is incorporated, the plausibility of specific risk hypotheses helps risk assessors sort through potentially large numbers of stressor-effect relationships and the ecosystem processes that influence them to identify those risk hypotheses most appropriate for the analysis phase. It is then that justifications for selecting and omitting selecting hypotheses are documented. Examples of risk hypotheses are provided in text note 3–11.

3.4.2. Conceptual Model Diagrams

Conceptual model diagrams may be based on theory and logic, empirical data, mathematical models, or probability models. They are useful tools for communicating important pathways in a clear and concise way and can be used to ask new questions about relationships that help generate plausible risk hypotheses. Some of the benefits gained by developing conceptual models are featured in text note 3–12.

Conceptual model diagrams frequently contain boxes and arrows to illustrate relationships (see figure 3–2 and Appendix C). When constructing these kinds of flow diagrams, it is helpful to use distinct and consistent shapes to distinguish stressors, assessment endpoints, responses, exposure routes, and ecosystem processes. Although flow diagrams are often used to illustrate conceptual models, there is no set configuration for conceptual model diagrams. Pictorial representations can be more effective (e.g., Bradley and Smith, 1989). Regardless of the configuration, a significant part of the usefulness of a diagram is linked to the detailed written descriptions and justifications for the pathways and relationships shown. Without this, diagrams can misrepresent the processes illustrated.

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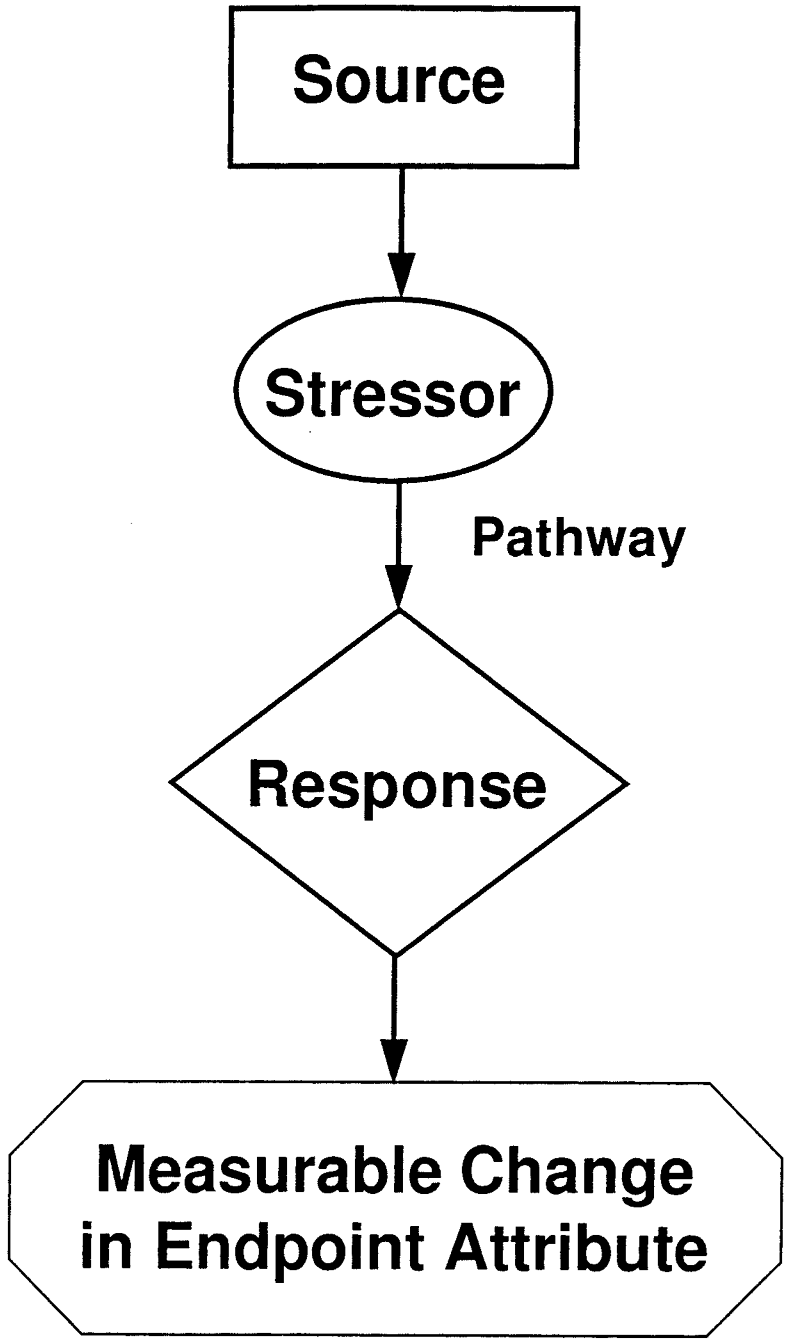

Figure 3-2. Elements of a conceptual model diagram. Illustrating the linkages between sources, stressors, and responses is an important function of the conceptual model diagram. However, the arrows in the diagram do not necessarily reflect the order in which this information is developed. See Appendix C for specific examples.

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When developing diagrams to represent a conceptual model, factors to consider include the number of relationships depicted, the comprehensiveness of the information, the certainty surrounding a pathway, and the potential for measurement. The number of relationships that can be depicted in one flow diagram depends on how comprehensive each relationship is. The more comprehensive, the fewer relationships that can be shown with clarity. Flow diagrams that highlight where data are abundant or scarce can provide insights on how the analyses should be approached and can be used to show the degree of confidence the risk assessor has in the relationship. Such flow diagrams can also help communicate why certain pathways were pursued and others were not.

Diagrams provide a working and dynamic representation of relationships. They should be used to explore different ways of looking at a problem before selecting one or several to guide analysis. Once the risk hypotheses are selected and flow diagrams drawn, they set the framework for final planning for the analysis phase.

3.4.3. Uncertainty in Conceptual Models

Conceptual model development may account for one of the most important sources of uncertainty in a risk assessment. If important relationships are missed or specified incorrectly, risks could be seriously under- or overestimated in the risk characterization phase. Uncertainty can arise from lack of knowledge on how the ecosystem functions, failing to identify and interrelate temporal and spatial parameters, not describing a stressor or suite of stressors, or not recognizing secondary effects. In some cases, little may be known about how a stressor moves through the environment or causes adverse effects. In most cases, multiple stressors are the norm and a source of confounding variables, particularly for conceptual models that focus on a single stressor. Opinions of experts on the appropriate conceptual model configuration may differ. While simplification and lack of knowledge may be unavoidable, risk assessors should document what is known, justify the model, and rank model components in terms of uncertainty (see Smith and Shugart, 1994).

Uncertainty associated with conceptual models can be reduced by developing alternative conceptual models for a particular assessment to explore possible relationships. In cases where more than one conceptual model is plausible, the risk assessor must decide whether it is feasible to follow separate models through the analysis phase or whether the models can be combined into a better conceptual model. It is important to revisit, and if necessary revise, conceptual models during risk assessments to incorporate new information and recheck the rationale. It is valuable to present conceptual models to risk managers to ensure the models communicate well and address key concerns the managers have. This check for completeness and clarity provides an opportunity to assess the need for changes before analysis begins.

Throughout the process of problem formulation, ambiguities, errors, and disagreements will occur, all of which contribute to uncertainty. Wherever possible, these sources of uncertainty should be eliminated through better planning. Because all uncertainty cannot be eliminated, a clear description of the nature of the uncertainties should be clearly summarized at the close of the problem formulation. Text note 3–13 provides recommendations for describing uncertainty in problem formulation.

The hypotheses considered most likely to contribute to risk are pursued in the analysis phase. As discussed previously, it is important to provide the rationale for selecting and omitting risk hypotheses and to acknowledge data gaps and uncertainties.

3.5. Analysis Plan

An analysis plan can be a usual final stage of problem formulation, particularly in the case of complex assessments. Here, risk hypotheses are evaluated to determine how they will be assessed using available and new data. The analysis plan can also delineate the assessment design, data needs, measures, and methods for conducting the analysis phase of the risk assessment. The analysis plan may be relatively brief or extensive depending on the nature of the assessment.

The analysis plan includes the most important pathways and relationships identified during problem formulation that will be pursued in the analysis phase. It is important for the risk assessor to describe what will be done and, in particular, what will not be done. It is important to address issues concerning the level of confidence needed for the management decision relative to the confidence that can be expected from an analysis in order to determine data needs and evaluate whether one analytical approach may be better than another. When new data are needed to conduct analyses, the feasibility of obtaining the data should be taken into account.

The selection of critical relationships in the conceptual model to pursue in analysis is based on several criteria, including:

- Availability of information.
- Strength of information about relationships between stressors and effects.
- The assessment endpoints and their relationship to ecosystem function.
- Relative importance or influence and mode of action of stressors.
- Completeness of known exposure pathways.

In situations where data are few and new data cannot be collected, it is possible to combine existing data with extrapolation models so that alternative data sources may be used. This allows the use of data from other locations or on other organisms where similar problems exist and data are available. For example, the relationship between nutrient availability and algal growth is well established. Although there will be differences in how the relationship is manifested based on the dynamics of a particular ecosystem, the relationship itself will tend to be consistent. When using data that require extrapolation, it is important to identify the source of the data, justify the extrapolation method and discuss major uncertainties apparent at this point.

Where data are not available, recommendations for new data collection should be part of problem formulation. An iterative, phased, or tiered approach (see text note 1–3) to the risk assessment may be selected to provide an opportunity for early management decisions on issues that can be addressed using available data. A decision to conduct a new iteration is based on the results of any previous iteration and proceeds using new data collected as specified in the analysis plan. When new data collection cannot be obtained, pathways that cannot be assessed are a source of uncertainty and should be described in the analysis plan.

3.5.1. Selecting Measures

It is in the analysis planning stage that measures are identified to evaluate the risk hypotheses. There are three categories of measures. Measures of effect are measures used to evaluate the response of the assessment endpoint when exposed to a stressor (formerly measurement endpoints). Measures of exposure are measures of how exposure may be occurring, including how a stressor moves through the environment and how it may co-occur with the assessment endpoint. Measures of ecosystem and receptor characteristics include ecosystem characteristics that influence the behavior and location of assessment endpoints, the distribution of a stressor, and life history characteristics of the assessment endpoint that may affect exposure or response to the stressor. These diverse measures increase in importance as the complexity of the assessment increases and are particularly important for risk assessments initiated to protect ecological values (see text notes 3–14 and 3–15 for more information).

Text note 3–16, which describes water quality criteria, provides one example of how goals, endpoints, and measures are related. Although water quality criteria are often considered risk-based, they do not measure exposure. Instead, the water quality criteria provide an effects benchmark for decisionmaking. Within that benchmark there are a number of assumptions about significance (e.g., aquatic communities will be protected by achieving a benchmark derived from individual species' toxicological responses to a single chemical) and exposure (e.g., 1-hour and 4-day exposure averages). Assumptions embedded in decision rules should be articulated (see section 3.5.2).

The analysis plan provides a synopsis of measures that will be used to evaluate risk hypotheses. Potential extrapolations, model characteristics, types of data (including quality), and planned analyses (with specific tests for different types of data) are described. The plan should discuss how the results will be presented upon completion. The analysis plan provides the basis for making selections of data sets that will be used for the risk assessment.

The plan includes explanations of how data analyses will distinguish among hypotheses, an explicit expression of the approach to be used, and justifications for the elimination of some hypotheses and selection of others. It includes the measures selected, analytical methods planned, and the nature of the risk characterization options and considerations that will be generated (e.g., quotients, narrative discussion, stressor-response curve with probabilities). An analysis plan is enhanced if it contains explicit statements for how measures were selected, what they are intended to evaluate, and which analyses they support. During analysis planning, uncertainties associated with selected measures and analyses are articulated and, where possible, plans for addressing them are made.

3.5.2. Relating Analysis Plans to Decisions

The analysis plan is a risk manager-risk assessor checkpoint and an appropriate time for technical review. Discussions between the risk assessors and risk managers can help ensure that the analyses will provide the type and extent of information that the manager can use for decisionmaking. These discussions may also identify what can and cannot be done based on the preliminary evaluation of problem formulation, including which relationships to portray for the risk management decision. A reiteration of the planning discussion is important to ensure that the appropriate balance among the requirements for the decision, data availability, and resource constraints is established for the risk assessment.

The elements of an analysis plan share significant similarities with the data quality objectives (DQO) process (see text note 3–17), which emphasizes identifying the problem by establishing study boundaries and determining necessary data quality, quantity, and applicability to the problem being evaluated. The DQO guidance is a valuable reference for risk assessors (U.S. EPA, 1994d).

The most important difference between problem formulation and DQO is the presence of a decision rule that defines a benchmark for a management decision before the risk assessment is completed. The decision rule step specifies the statistical parameter that characterizes the population, specifies the action level for the study, and combines outputs from the previous DQO steps into an ''if * * * then'' decision rule that defines conditions under which the decision maker will choose alternative options. This approach provides the basis for establishing null and alternative hypotheses appropriate for statistical testing for significance. While this approach is appropriate for some risk assessments, many risk assessments are not based on benchmark decisions. Presentation of stressor-response curves with uncertainty bounds will be more appropriate than statistical testing of decision criteria where risk managers must evaluate the range of stressor effects to which they compare a range of possible management options.

The analysis plan is the final synthesis before the risk assessment proceeds. It summarizes what has been done during problem formulation, shows how the plan relates to management decisions that must be made, and indicates how data and analyses will be used to estimate risks. When it is determined that the problem is clearly defined and there are enough data to proceed, analysis begins.

4. Analysis Phase

The analysis phase consists of the technical evaluation of data to reach conclusions about ecological exposure and the relationships between the stressor and ecological effects. During analysis, risk assessors use measures of exposure, effects, and ecosystem and receptor attributes to evaluate questions and issues that were identified in problem formulation. The products of analysis are summary profiles that describe exposure and the stressor-response relationship. When combined, these profiles provide the basis for reaching conclusions about risk during the risk characterization phase.

The conceptual model and analysis plan developed during problem formulation provide the basis for the analysis phase. By the start of analysis, the assessor should know which stressors and ecological effects are the focus of investigation and whether secondary exposures or effects will be considered. In the analysis plan, the assessor identified the information needed to perform the analysis phase. By the start of analysis, these data should be available (text note 4–1).

The analysis phase is composed of two principal activities, the characterization of exposure and characterization of ecological effects (figure 4–1). Both activities begin by evaluating data (i.e., the measures of exposure, ecosystem and receptor characteristics, and effects) in terms of their scientific credibility and relevance to the assessment endpoint and conceptual model (discussed in section 4.1). In exposure characterization (section 4.2), these data are then analyzed to describe the source, the distribution of the stressor in the environment, and the contact or co-occurrence of the stressor with ecological receptors. In ecological effects characterization (section 4.3), data are analyzed to describe the relationship between the stressor and response and to evaluate the evidence that exposure to the stressor causes the response (i.e., stressor-response analyses). In many cases, extrapolation will be necessary to link the measures of effect with the assessment endpoint.

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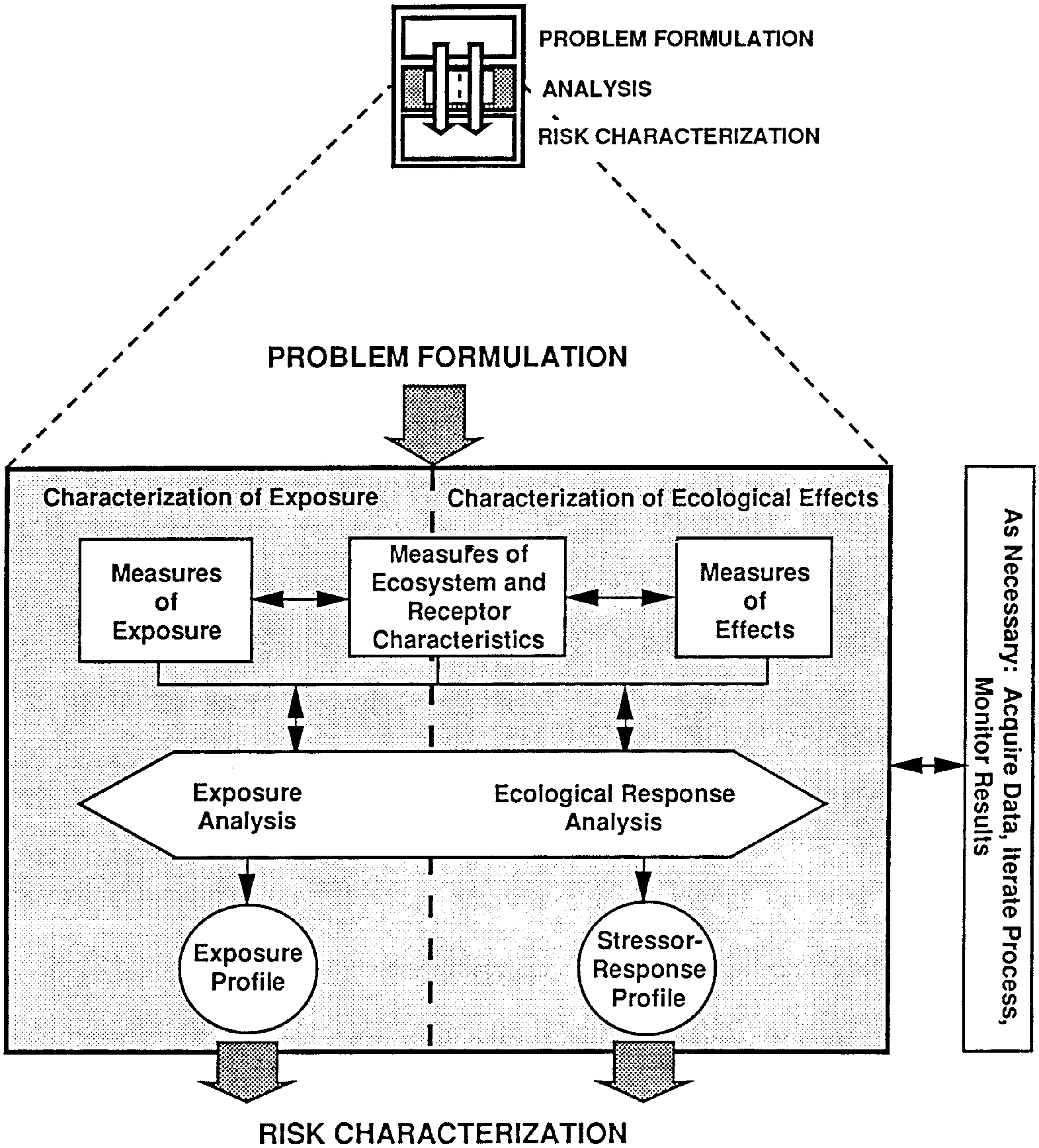

Figure 4-1. Analysis phase.

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Conclusions about exposure and the relationship between the stressor and response are summarized in profiles. The exposure and stressor-response profiles (sections 4.2.2 and 4.3.2, respectively) provide the opportunity to review what has been learned during the analysis phase and summarize this information in the most useful format for risk characterization. Depending on the risk assessment, these profiles may take the form of a written document or modules of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the purpose of these profiles is to ensure that the information needed for risk characterization has been collected and evaluated.

This process is intended to be flexible, and interaction between the ecological effects characterization and exposure characterization is recommended. When secondary stressors and effects are of concern, exposure and effects analyses are conducted iteratively for different ecological entities, and the analyses can become so intertwined that they are difficult to differentiate. The bottomland hardwoods example (Appendix D) illustrates this type of assessment. This assessment examined potential changes in the plant and animal communities under different flooding scenarios. The stressor-response and exposure analyses were combined within the FORFLO model for primary effects on the plant community and within the Habitat Suitability Index for secondary effects on the animal community.

In addition, the distinction between the analysis phase and risk estimation can become blurred. For example, the model results developed for the bottomland hardwoods example were used directly in risk characterization.

The nature of the stressor (that is, whether it is chemical, physical, or biological) will influence the types of analyses conducted and the details of implementation. Thus, the results of the analysis phase may range from highly quantitative to qualitative, depending on the stressor and the scope of the assessment. The estimation of exposure to chemicals emphasizes contact and uptake into the organism, and the estimation of effects often entails extrapolation from test organisms to the organism of interest. For physical stressors, the initial disturbance may be most closely related to the assessment endpoint (e.g., change of wetland to upland). In many cases, however, secondary effects (e.g., effects on wildlife that use the wetland) are the principal concern. The point of view taken during the analysis phase will depend on the assessment endpoints identified during problem formulation. Because adverse effects can occur even if receptors do not physically contact disturbed habitat, exposure analyses may emphasize co-occurrence with physical stressors rather than contact. For biological stressors, exposure analysis evaluates entry, dispersal, survival, and reproduction (Orr et al., 1993). Because biological stressors can reproduce, interact with other organisms, and evolve over time, exposure and effects cannot be quantified with confidence. Accordingly, exposure and effects are often assessed qualitatively by eliciting expert opinion (Simberloff and Alexander, 1994).

4.1. Evaluating Data and Models for Analysis

In problem formulation, the assessor identifies the information needed to perform the analysis phase and plans for collecting new data. The first step of the analysis phase is the critical evaluation of data and models to ensure that they can support the risk assessment. The sources and evaluation of data and models are discussed in sections 4.1.1 and 4.1.2, respectively. The evaluation of uncertainty, an important consideration when evaluating data and also throughout the analysis phase, is discussed in section 4.1.3.

4.1.1. Strengths and Limitations of Different Types of Data

The analysis phase relies on the measures identified in the analysis plan; these may come from laboratory or field studies or may be produced as output from a model. Data may have been developed for a specific risk assessment or for another purpose. A strategy that builds on the strengths of each type of data can improve confidence in the conclusions of a risk assessment.

Both laboratory and field studies (including field experiments and observational studies) can provide useful data for risk assessment. Because conditions can be controlled in laboratory studies, responses can be less variable and smaller differences easier to detect. However, the controls may limit the range of responses (for example, animals cannot seek alternate food sources), so they may not reflect responses in the environment. Field surveys are usually more representative of both exposures and effects (including secondary effects) found in natural systems than are estimates generated from laboratory studies or theoretical models. However, because conditions are not controlled, variability may be higher and it may be difficult to detect differences. Field studies are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. In addition, the presence of confounding stressors can make it difficult to attribute observed effects to specific stressors. Preferred field studies use designs that minimize effects of potentially confounding factors. Intermediate between laboratory and field are studies that use environmental media collected from the field to conduct studies of response in the laboratory. Such studies may improve the power to detect differences and may be designed to provide evidence of causality.

Most data will be reported as measurements for single variables such as a chemical concentration or the number of dead organisms. In some cases, however, variables are combined into indices, and the index values are reported. Several indices are used to evaluate effects, for example, the rapid bioassessment protocols (U.S. EPA, 1989a) and the Index of Biotic Integrity, or IBI (Karr, 1981; Karr et al., 1986). These have several advantages (Barbour et al., 1995), including the ability to:

- Provide an overall indication of biological condition by incorporating many attributes of system structure and function, from individual to ecosystem levels.
- Evaluate responses from a broad range of anthropogenic stressors.
- Minimize the limitations of individual metrics for detecting specific types of responses.

Although indices are very useful, they have several drawbacks, many of which are associated with combining heterogeneous variables. For example, the final value may depend strongly on the function used to combine variables. Some indices (e.g., the IBI) combine only measures of effects. Differential sensitivity or other factors may make it difficult to attribute causality when many response variables are combined. Such indices may need to be separated into their components to investigate causality (Suter, 1993b; Ott, 1978). Interpretation becomes even more difficult when an index combines measures of exposure and effects because double-counting may occur or changes in one variable can mask changes in another. Exposure and effects measures may need to be separated in order to make appropriate conclusions. For these reasons, professional judgment plays a critical role in developing and applying indices.

Experience from similar situations is also an important data source that is particularly useful when predicting effects of stressors that have not yet been released. For example, lessons learned from past experiences with related organisms are often critical in trying to predict whether an organism will survive, reproduce, and disperse in a new environment. Another example is the evaluation of toxicity of new chemicals through the use of structure-activity relationships, or SARs (Auer et al., 1994; Clements and Nabholz, 1994). The simplest application of SARs is to identify a suitable analog for which data are available to estimate the toxicity of the compound for which data are lacking. More advanced applications involve the use of quantitative structure-activity relationships (QSARs). QSARs describe the relationships between chemical structures and specific biological effects and are derived using information on sets of related chemicals (Lipnick, 1995; Cronin and Dearden, 1995). The use of analogous data without knowledge of the underlying processes may substantially increase the uncertainty in the risk assessment (e.g., Bradbury, 1994); however, these data may be the only option available.

While models are often developed and used as part of the risk assessment, sometimes the risk assessor relies on output of a previously developed model as input to the risk assessment. Models are particularly useful when measurements cannot be taken, for example when the assessment is predicting the effects of a chemical yet to be manufactured. Models can also provide estimates for times or locations that are impractical to measure and provide a basis for extrapolating beyond the range of observation. Starfield and Bleloch (1991) caution that ''the quality of the model does not depend on how realistic it is, but on how well it performs in relation to the purpose for which it was built.'' Thus, the assessor must review the questions that need to be answered and then ensure that a model can answer those questions. Because models are simplifications of reality, they may not include important processes for a particular system and may not reflect every condition in the real world. In addition, a model's output is only as good as the quality of its input variables, so critical evaluation of input data is important, as is comparing model outputs with measurements in the system of interest whenever possible.

Data and models for risk assessment are often developed in a tiered fashion (also see text note 1–3). For example, simple models that err on the side of conservatism may be used first, followed by more elaborate models that provide more realistic estimates. Effects data may also be collected by using a tiered approach. Short-term tests designed to evaluate effects such as lethality and immobility may be conducted first. If the chemical exhibits high toxicity or a preliminary characterization indicates a risk, then more expensive, longer-term tests that measure sublethal effects such as changes to growth and reproduction can be conducted. Later tiers may employ multispecies tests or field experiments. It is important to evaluate tiered data in light of the decision they are intended to support; data collected for early tiers may not be able to support more sophisticated needs.

4.1.2. Evaluating Measurement or Modeling Studies

Much of the information used in the analysis phase is available through published or unpublished studies that describe the purpose of the study, the methods used to collect data, and the results. Evaluating the utility of these studies relies on careful comparison of the objectives of the studies with the objectives of the risk assessment. In addition, study methods are examined to ensure that the intended objectives were met and that the data are of sufficient quality to support the risk assessment. Confidence in the information and the implications of using different studies should be described during risk characterization, when the overall confidence in the assessment is discussed. In addition, the risk assessor should identify areas where existing data do not meet risk assessment needs. In these cases, we recommend collecting new data.

EPA is in the process of adopting the American Society for Quality Control's E–4 guidelines for assuring environmental data quality throughout the Agency (ASQC, 1994) (text note 4–2). These guidelines describe procedures for collecting new data and provide a valuable resource for evaluating existing studies. (Readers are also referred to Smith and Shugart, 1994; U.S. EPA, 1994f; and U.S. EPA, 1990, for more information on evaluating data and models.)

A study's documentation directly influences the ability to evaluate its utility for risk assessment. Studies should contain sufficient information so that results can be reproduced, or at least so the details of the author's work can be accessed and evaluated. An additional advantage is the ability to access findings in their entirety; this provides the opportunity to conduct additional analyses of the data, if needed. For models, a number of factors increase the accessibility of methods and results. These begin with model code and documentation availability. Reports describing model results should include all important equations, tables of all parameter values, a description of any parameter estimation techniques, and tables or graphs of results.

Papers or reports describing studies may not provide all of the information needed to evaluate a study's utility for risk assessment. Assessors are encouraged to communicate with the principal investigator or other study participants to gain information on study plans and their implementation. Questions useful for evaluating studies are shown in text note 4–3.

4.1.2.1. Evaluating the Purpose and Scope of the Study

The assessor must often evaluate the utility of a study that was designed for a purpose other than risk assessment. In these cases, it is important that the objectives and scope of the original study be examined to evaluate their compatibility with the objectives and needs of the current risk assessment.

An examination of objectives can identify important uncertainties and ensure that the information is used appropriately in the assessment. An example is the evaluation of studies that measure condition (e.g., stream surveys, population surveys). While the measurements used to evaluate condition may be the same as the effects measures identified in problem formulation, to support a causal argument, effects measures must be linked with stressors. In the best case, this means that the stressor should be measured at the same time and place as the effect.

Similarly, a model may have been developed for purposes other than risk assessment. The model description should include the intended application, theoretical framework, underlying assumptions, and limiting conditions. This information can help assessors identify important limitations in its application for risk assessment. For example, a model developed to evaluate chemical transport in the water column alone may have limited utility for a risk assessment of a chemical that partitions readily into sediments.

The variables and conditions examined by studies should also be compared with those variables and conditions identified during problem formulation. In addition, the range of variability explored in the study should be compared with the range of variability of interest for the risk assessment. For example, a study that examines habitat needs of an animal during the winter may miss important breeding-season requirements. In general, studies that minimize the amount of extrapolation needed are preferred. These are the studies that are designed to represent:

- The measures identified in the analysis plan (i.e., measures of exposure, effects, and ecosystem and receptor characteristics).
- The time frame of interest, considering seasonality and intermittent events.
- The ecosystem and location of interest.
- The environmental conditions of interest.
- The exposure route of interest.

4.1.2.2. Evaluating the Design and Implementation of the Study

The design and implementation of the study are evaluated to ensure that the study objectives were met and that the information is of sufficient quality to support the purposes of the risk assessment. The study design provides insight into the sources and magnitude of uncertainty associated with the results (see section 4.1.3 for further discussion of uncertainty). Among the most important design issues for studies of effects is whether a study had sufficient power to detect important differences or changes. Because this information is rarely reported (Peterman, 1990), the assessor may need to calculate the magnitude of an effect that could be detected under the study conditions (Rotenberry and Wiens, 1985).

Risk assessors should evaluate evidence that the study was conducted properly. For laboratory studies, this may mean determining whether test conditions were properly controlled and control responses were within acceptable bounds. For field studies, issues include the identification and control of potentially confounding variables and the careful selection of reference sites. For models, issues include the program's structure and logic and the correct specification of algorithms in the model code (U.S. EPA, 1994f).

Study evaluation is easier if a standard method or standard quality assurance/quality control (QA/QC) protocols are available and followed by the study. However, the assessor still needs to consider whether the precision and accuracy goals identified in the standard method were achieved and whether these goals are appropriate for the purposes of the risk assessment. For example, detection limits identified for one environmental matrix may not be achievable for another and may be higher than concentrations of interest for the risk assessment. Study results can still be useful even if a standard method was not used. However, it does place an additional burden on both the authors and the assessors to provide and evaluate evidence that the study was conducted properly.

4.1.3. Evaluating Uncertainty

Uncertainty evaluation is an ongoing theme throughout the analysis phase. The objective is to describe, and, where possible, quantify what is known and not known about exposure and effects in the system of interest. Uncertainty analyses increase credibility by explicitly describing the magnitude and direction of uncertainties, and they provide the basis for efficient data collection of or application of refined methods.

U.S. EPA (1992d) discusses sources of uncertainty that arise during the evaluation of information and conceptual model development (combined under the subject of scenario uncertainty), when evaluating the value of a parameter (e.g., an environmental measurement or the results of a toxicity test), and during the development and application of models. Uncertainty in conceptual model development is discussed in section 3.4.3. Many of the sources of uncertainty discussed by EPA (U.S. EPA, 1992d) are relevant to characterizing both exposure and ecological effects; these sources and example strategies for the analysis phase are shown in table 4–1.

TABLE 4–1.—UNCERTAINTY EVALUATION IN THE ANALYSIS PHASE

Source of uncertainty	Example analysis phase strategies	Specific example
Unclear communication	Contact principal investigator or other study participants if objectives and methods of literature studies are unclear. Document decisions made during the course of the assessment.	Clarify whether the study was designed to characterize local populations or regional populations. Discuss rationale for selecting the critical toxicity study.
Descriptive errors	Verify that data sources followed appropriate QA/QC procedures.	Double-check calculations and data entry.
Variability	Describe heterogeneity using point estimates (e.g., central tendency and high end) or by constructing probability or frequency distributions. Differentiate from uncertainty due to lack of knowledge.	Display differences in species sensitivity using a cumulative distribution function.
Data gaps	Describe approaches used for bridging gaps and their rationales. Differentiate science-based judgments from policy-based judgments.	Discuss rationale for using a factor of 10 to extrapolate between a LOAEL and a NOAEL.
Uncertainty about a quantity's true value	Use standard statistical methods to construct probability distributions or point estimates (e.g., confidence limits). Evaluate power of designed experiments to detect differences. Consider taking additional data if sampling error is too large. Verify location of samples or other spatial features	Present the upper confidence limit on the arithmetic mean soil concentration, in addition to the best estimate of the arithmetic mean. Ground-truth remote sensing data.
Model structure uncertainty (process models)	Discuss key aggregations and model simplifications. Compare model predictions with data collected in the system of interest.	Discuss combining different species into a group based on similar feeding habits.

TABLE 4–1.—UNCERTAINTY EVALUATION IN THE ANALYSIS PHASE—Continued

Source of uncertainty	Example analysis phase strategies	Specific example
Uncertainty about a model's form (empirical models).	Evaluate whether alternative models should be combined formally or treated separately. Compare model predictions with data collected in the system of interest.	Present results obtained using alternative models. Compare results of a plant uptake model with data collected in the field.

Sources of uncertainty that are factors primarily when evaluating information include unclear communication of the information to the assessor, unclear communication about how the assessor handled the information, and errors in the information itself (descriptive errors). These sources are usually characterized by critically examining sources of information and documenting the rationales for the decisions made when handling it. The discussion should allow the reader to make an independent judgment about the validity of the decisions reached by the assessor.

Sources of uncertainty that arise primarily when estimating the value of a parameter include variability, uncertainty about a quantity's true value, and data gaps. The term variability is used here to describe the true heterogeneity in a characteristic influencing exposure or effects. Examples include the variability in soil organic carbon, seasonal differences in animal diets, or differences in chemical sensitivity among different species. This heterogeneity is usually described during uncertainty analysis, although heterogeneity may not reflect a lack of knowledge and cannot usually be reduced by further measurement. Variability can be described by presenting a distribution or specific percentiles from it (e.g., mean and 95th percentile).

Uncertainty about a quantity's true value may include uncertainty about its magnitude, location, or time of occurrence. This uncertainty can usually be reduced by taking additional measurements. Uncertainty about a quantity's true magnitude is usually described by sampling error (or variance in experiments) or measurement error. When the quantity of interest is biological response, sampling error can greatly influence the ability of the study to detect effects. Properly designed studies will specify sample sizes that are sufficiently large to detect important signals. Unfortunately, many studies have sample sizes that are too small to detect anything but gross changes (Smith and Shugart, 1994; Peterman, 1990). The discussion should highlight situations where the power to detect difference is low. Meta-analysis has been suggested as a way to combine results from different studies to improve the ability to detect effects (Laird and Mosteller, 1990; Petitti, 1994). However, these approaches have been applied primarily in the arena of human epidemiology and are still controversial (Mann, 1990).

Interest in quantifying spatial uncertainty has increased with the increasing use of geographic information systems. Strategies include verifying the locations of remotely sensed features, ensuring that the spatial resolution of data or a method is commensurate with the needs of the assessment, and using methods to describe and use the spatial structure of data (e.g., Cressie, 1993).

Nearly every assessment encounters situations where data are unavailable or where information is available on parameters that are different from those of interest for the assessment. Examples include using laboratory animal data to estimate a wild animal's response or using a bioaccumulation measurement from an ecosystem other than the one interest. These data gaps are usually bridged based on a combination of scientific data or analyses, scientific judgement, and policy judgement. For example, in deriving an ambient water quality criterion (text note 3–16), data and analyses are used to construct distributions of species sensitivity for a particular chemical. Scientific judgment is used to infer that species selected for testing will adequately represent the range of sensitivity of species in the environment. Policy judgment is used to define the extent to which individual species should be protected (e.g., 90 vs 95 percent of the species). It is important to differentiate among these elements when key assumptions and the approach used are documented.

In some circumstances scientists may disagree on the best way to bridge data gaps. This lack of consensus can increase uncertainty. Confidence can be increased through consensus building techniques such as peer reviews, workshops, and other methods to elicit expert opinion. Data gaps can often be filled by completing additional studies on the unknown parameter. Opportunities for reducing this source of uncertainty should be noted and carried through to risk characterization. Data gaps that preclude the analysis of exposure or ecological effects should also be noted and discussed in risk characterization.

An important objective of characterizing uncertainty in the analysis phase is to distinguish variability from uncertainties arising from lack of knowledge (e.g., uncertainty about a quantity's true value) (U.S. EPA, 1995c). This distinction facilitates the interpretation and communication of results. For example, in their food web models of herons and mink, MacIntosh et al. (1994) separated variability expected among feeding habits of individual animals from the uncertainty in the mean concentration of chemical in prey species. In this way, the assessors could place error bounds on the distribution of exposure among the animals using the site and estimate the proportion of the animal population that might exceed a toxicity threshold.

Sources of uncertainty that arise primarily during the development and application of models include the structure of process models and the description of the relationship between two or more variables in empirical models. Process model description should include key assumptions, simplifications, and aggregations of variables (see text note 4–4). Empirical model descriptions should include the rationale for selection, and statistics on model performance (e.g., goodness of fit). Uncertainty in process or empirical models can be quantitatively evaluated by comparing model results to measurements taken in the system of interest or by comparing the results obtained using different model alternatives.

Methods for analyzing and describing uncertainty can range from simple to complex. The calculation of one or more point estimates is one of the most common approaches to presenting analysis results; point estimates that reflect different aspects of uncertainty can have great value if appropriately developed and communicated. Classical statistical methods (e.g., confidence limits, percentiles) can be readily applied to describing uncertainty in parameters. When a modeling approach is used, sensitivity analysis can be used to evaluate how model output changes with changes in input variables, and uncertainty propagation can be analyzed to examine how uncertainty in individual parameters can affect the overall uncertainty of the assessment. The availability of software for Monte-Carlo analysis has greatly increased the use of probabilistic methods; readers are encouraged to follow best practices that have been suggested (e.g., Burmaster and Anderson, 1994; Haimes et al. 1994). Other methods (e.g., fuzzy mathematics, Bayesian methodologies) are available, but have not yet been extensively applied to ecological risk assessment (Smith and Shugart, 1994). These guidelines do not endorse the use of any one method over others and note that the poor execution of any method can obscure rather than clarify the impact of uncertainty on an assessment's results. No matter what technique is used, the sources of uncertainty discussed above should be addressed.

4.2. Characterization of Exposure

Exposure characterization describes the contact or co-occurrence of stressors with ecological receptors. The characterization is based on measures of exposure and of ecosystem and receptor characteristics (the evaluation of this information is discussed in section 4.1). These measures are used to analyze stressor sources, their distribution in the environment, and the extent and pattern of contact or co-occurrence (discussed in section 4.2.1). The objective is to produce a summary exposure profile (section 4.2.2) that identifies the receptor (i.e., the exposed ecological entity), describes the course a stressor takes from the source to the receptor (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact. The profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur.

The exposure profile is combined with an effects profile (discussed in section 4.3.2) to estimate risks. For the results to be useful, they must be compatible with the stressor-response relationship generated in the effects characterization.

4.2.1. Exposure Analyses

Exposure is analyzed by describing the source and releases, the distribution of the stressor in the environment, and the extent and pattern of contact or co-occurrence. The order of discussion of these topics is not necessarily the order in which they are evaluated in a particular assessment. For example, the assessor may start with information about tissue residues, and attempt to link these residues with a source.

4.2.1.1. Describe the Source

A source description identifies where the stressor originates, describes what stressors are generated, and considers other sources of the stressor. Exposure analyses may start with the source when it is known, but some analyses may begin with known exposures and attempt to link them to sources, while other analyses may start with known stressors and attempt to identify sources and quantify contact. The source is the first component of the exposure pathway and significantly influences where and when stressors eventually will be found. In addition, many management alternatives focus on modifying the source. Text note 4–5 provides some useful questions.

A source can be defined in several ways—as the place where the stressor is released (e.g., a smoke stack, historically contaminated sediments) or the management practice or action (e.g., dredging) that produces stressors. In some assessments, the original source no longer exists and the source is defined as the current origin of the stressors. For example, the source may be defined as contaminated sediments because the industrial plant that produced the contaminants no longer operates.

In addition to identifying the source, the assessor describes the generation of stressors in terms of intensity, timing, and location. The location of the source and the environmental medium that first receives stressors are two attributes that deserve particular attention. In addition, the source characterization should consider whether other constituents emitted by the source influence transport, transformation, or bioavailability of the stressor of interest. For example, the presence of chloride in the feedstock of a coal-fired power plant influences whether mercury is emitted in divalent (e.g., as mercuric chloride) or elemental form (Meij, 1991). In the best case, stressor generation is measured or modeled quantitatively; however, sometimes it can only be qualitatively described.

Many stressors have natural counterparts or multiple sources, and the characterization of these other sources can be an important component of the analysis phase. For example, many chemicals occur naturally (e.g., most metals), are generally widespread due to other sources (e.g., polycyclic aromatic hydrocarbons in urban ecosystems), or may have significant sources outside the boundaries of the current assessment (e.g., atmospheric nitrogen deposited in Chesapeake Bay). Many physical stressors also have natural counterparts. For example, construction activities may add fine sediments to a stream in addition to those from a naturally undercut bank. In addition, human activities may change the magnitude or frequency of natural disturbance cycles. For example, development may decrease the frequency but increase the severity of fires or may increase the frequency and severity of flooding in a watershed.

The way multiple sources are evaluated during the analysis phase depends on the objectives of the assessment articulated during problem formulation. Options include (in order of increasing complexity):

- Focus only on the source under evaluation and calculate incremental risks attributable to that source (common for assessments initiated with an identified source or stressor).
- Consider all sources of a stressor and calculate total risks attributable to that stressor. Relative source attribution can be accomplished as a separate step (common for assessments initiated with an observed effect or an identified stressor).
- Consider all stressors influencing an assessment endpoint and calculate cumulative risks to that endpoint (common for assessments initiated because of concern for an ecological value).

Source characterization can be particularly important for new biological stressors, since many of the strategies for reducing risks focus on preventing entry in the first place. Once the source is identified, the likelihood of entry may be characterized qualitatively. For example, in their analysis of risks from importation of Chilean logs, the assessment team concluded that the beetle *Hylurgus ligniperda* had a high potential for entry into the United States. They based this conclusion on the fact that they are attracted to freshly cut logs and tend to burrow under the bark and thus would be protected during transport (USDA, 1993).

The description of the source can set the stage for the second objective of exposure analysis, which is describing the distribution of the stressor in the environment.

4.2.1.2. Describe the Distribution of the Stressor or Disturbed Environment

The second objective of exposure analyses is to describe the spatial and temporal distribution of the stressor in the environment. For physical stressors that directly alter or eliminate portions of the environment, the assessor describes the temporal and spatial distribution of the disturbed environment. Because exposure occurs where receptors co-occur with or contact stressors in the environment, characterizing the spatial and temporal distribution of a stressor is a necessary precursor to estimating exposure. The stressor's distribution in the environment is described by evaluating the pathways that stressors take from the source as well as the formation and subsequent distribution of secondary stressors.

Evaluating Transport Pathways. There are many pathways by which stressors can be transported in the environment (see text note 4–7). An evaluation of transport pathways can help ensure that measurements are taken in the appropriate media and locations and that models include the most important processes.

For chemical stressors, the evaluation of pathways usually begins by determining into which media a chemical will partition. Key considerations include physicochemical properties such as solubility and vapor pressure. For example, lipophilic chemicals tend to be found in environmental compartments with higher proportions of organic carbon, such as soils, sediments, and biota. From there, the evaluation may examine the transport of the contaminated medium. Because constituents of chemical mixtures may have different properties, it is important to consider how the composition of a mixture may change over time or as it moves through the environment. Guidance on evaluating the fate and transport of chemicals is beyond the scope of these guidelines; readers are referred to the exposure assessment guidelines (U.S. EPA, 1992d) for additional information.

The attributes of physical stressors may also influence where the stressors will go. For example, the size of silt particles determines where they will eventually deposit in a stream. Physical stressors that eliminate ecosystems or portions of them (e.g., logging activity or the construction of dams or parking lots) may require no modeling of pathways—the wetland is filled, the fish are harvested, or the valley is flooded. For these direct disturbances, the challenge is usually to evaluate the formation of secondary stressors and the effects associated with the disturbance.

The dispersion of biological stressors has been described in two ways, as diffusion and jump-dispersal (Simberloff and Alexander, 1994). Diffusion involves a gradual spread from the establishment site and is a function primarily of reproductive rates and motility. The other movement pattern, jump-dispersal, involves erratic spreads over periods of time, usually by means of a vector. The gypsy moth and zebra mussel have spread this way; the gypsy moth via egg masses on vehicles and the zebra mussel via boat ballast water. Biological stressors can use both diffusion and jump-dispersal strategies, and often one or more mechanisms are important. This makes dispersal rates very difficult to predict. Key considerations include the availability of vectors, whether the organism has natural attributes that enhance dispersal (e.g., ability to fly, adhere to objects, disperse reproductive units), and the habitat or host needs of the organism.

For biological stressors, assessors must consider the additional factors of survival and reproduction. There is a wide range of strategies organisms use to survive in adverse conditions, for example, fungi form resting stages such as sclerotia and chlamydospores and some amphibians became dormant during drought. The survival of some organisms can be measured to some extent under laboratory conditions. However, it may be impossible to determine how long some resting stages (e.g., spores) can survive under adverse conditions; many can remain viable for years. Similarly, reproductive rates may vary substantially, depending on specific environmental conditions. Therefore, while life-history data such as temperature and substrate preferences, important predators, competitors or diseases, habitat needs, and reproductive rates are of great value, they must be interpreted with caution.

Ecosystem characteristics influence the transport of all types of stressors. The challenge is to determine the particular aspects of the ecosystem that are most important. In some cases, ecosystem characteristics that influence distribution are known. For example, fine sediments tend to accumulate in areas of low energy in streams such as pools and backwaters. In other cases, much more professional judgment is needed. For example, when evaluating the likelihood that an introduced organism will become established, it is useful to know whether the ecosystem is generally similar to or different from the one where the biological stressor originated. In this case, professional judgment is needed to determine which characteristics of the current and original ecosystems should be compared.

Evaluating Secondary Stressors. The creation of secondary stressors can greatly alter conclusions about risk. Secondary stressors can be formed through biotic or abiotic transformation processes and may be of greater or lesser concern than the primary stressor. Evaluating the formation of secondary stressors is usually done as part of exposure characterization; however, coordination with the ecological effects characterization is important to ensure that all potentially important secondary stressors are evaluated.

For chemicals, the evaluation of secondary stressors usually focuses on metabolites or degradation products or chemicals formed through abiotic processes. For example, microbial action increases the bioaccumulation of mercury by transforming it from inorganic form to organic forms. Many azo dyes are not toxic because of their large molecular size but, in an anaerobic environment, the polymer is hydrolyzed into more toxic water-soluble units. In addition, secondary stressors can be formed through ecosystem processes. For example, nutrient inputs into an estuary can decrease dissolved oxygen concentrations because they increase primary production and subsequent decomposition. While the possibility and rates of transformation can be investigated in the laboratory, rates in the field may differ substantially, and some processes may be difficult or impossible to replicate in a laboratory. When evaluating field information, though, it may be difficult to distinguish between transformation processes (e.g., degradation of oil constituents by microorganisms) and transport processes (e.g., loss of oil constituents through volatilization).

Disturbances can also generate secondary stressors, and identifying the specific consequences that will affect the assessment endpoint can be a difficult task. For example, the removal of riparian vegetation can generate many secondary stressors, including increased nutrients, stream temperature, sedimentation, and altered stream flow. However, it may be the resulting increase in stream temperature that is the primary cause of adult salmon mortality in a particular stream.

The distribution of stressors in the environment can be described using measurements, models, or a combination of the two. If stressors have already been released, direct measurements of environmental media or a combination of modeling and measurement is preferred. However, a modeling approach may be necessary if the assessment is intended to predict future scenarios or if measurements are not possible or practicable. Considerations for evaluating data collection and modeling studies are discussed in section 4.1. For chemical stressors, we also refer readers to the exposure assessment guidelines (U.S. EPA, 1992d). For biological stressors, the distribution in the environment is difficult to predict quantitatively. If measurements in the environment cannot be taken, distribution can be evaluated qualitatively by considering the potential for transport, survival, and reproduction (see above).

By the end of this step, the environmental distribution of the stressor or the disturbed environment should be described. This description can be an important precursor to the next objective of exposure analysis—estimating the contact or co-occurrence of the stressor with ecological entities. In cases where the extent of contact is known, describing the environmental distribution of the stressor can help identify potential sources, and ensure that all important exposures have been addressed. In addition, by identifying the pathways a stressor takes from a source, the second component of an exposure pathway is described.

4.2.1.3. Describe Contact or Co-occurrence

The third objective of the exposure analysis is to describe the extent and pattern of co-occurrence or contact between a stressor and a receptor (i.e., exposure). The objective of this step is to describe the intensity and temporal and spatial extent of exposure in a form that can be compared with the stressor-response profile generated in the effects assessment. The description of exposure is a critical element of estimating risk—if there is no exposure, there can be no risk. Questions for describing contact or co-occurrence are shown in text note 4–8.

Exposure can be described in terms of co-occurrence of the stressor with receptors, of the actual contact of a stressor with receptors, or of the uptake of a stressor into a receptor. The terms by which exposure is described depend on how the stressor causes adverse effects. Co-occurrence is particularly useful for evaluating stressors that can cause effects without actually contacting ecological receptors. For example, whooping cranes use sandbars in rivers for their nesting areas, and they prefer sandbars with unobstructed views. Manmade obstructions, such as bridges, can interfere with nesting behavior without ever actually contacting the birds. Most stressors, however, must contact receptors to cause an effect. For example, flood waters must contact tree roots before their growth is impaired. Finally, some stressors must not only be contacted, but also must be internally absorbed. For example, a toxicant that causes liver tumors in fish must be absorbed through the gills and reach the target organ to cause the effect.

Co-occurrence is evaluated by comparing the distribution of the stressor with the distribution of the ecological receptor. For example, maps of the stressor may be overlaid with maps of ecological receptors (e.g., the placement of bridges overlaid on maps showing habitat historically used for crane nests). The increased availability of geographic information systems (GIS) has provided new tools for evaluating co-occurrence.

Contact is a function of the amount of a stressor in an environmental medium and activities or behavior that brings receptors into contact with the stressor. For biological stressors, this step relies extensively on professional judgment; contact is often assumed to occur in areas where the two overlap. For chemicals, contact is quantified as the amount of a chemical ingested, inhaled, or in material applied to the skin (i.e., the potential dose). In its simplest form, it is quantified as an environmental concentration, with the assumptions that the chemical is well mixed and that the organism contacts a representative concentration. This approach is commonly used for respired media (e.g., water for aquatic organisms, air for terrestrial organisms). For ingested media (e.g., food, soil), another common approach combines modeled or measured concentrations of the contaminant with assumptions or parameters describing the contact rate (U.S. EPA, 1993c) (see text note 4–9).

Uptake is evaluated by considering the amount of stressor that is internally absorbed into an organism. Uptake is a function of the stressor (e.g., a chemical's form or valence state), the medium (e.g., sorptive properties or presence of solvents), the biological membrane (e.g., integrity, permeability), and the organism (e.g., sickness, active uptake) (Suter et al., 1994). Because of interactions among these four factors, uptake will vary on a situation-specific basis. Uptake is usually assessed by modifying an estimate of contact with a factor indicating the proportion of the stressor that is available for uptake (i.e., the bioavailable fraction) or actually absorbed. Absorption factors and bioavailability measured for the chemical, ecosystem, and organism of interest are preferred. Internal dose can also be evaluated by using a pharmacokinetic model or by measuring biomarkers or residues in receptors (see text note 4–10). Most stressor-response relationships express the amount of stressor in terms of media concentration or potential dose rather than internal dose; this limits the utility of using estimates of uptake for risk estimation. However, biomarkers and tissue residues can provide valuable confirmatory evidence that exposure has occurred, and tissue residues in prey organisms can be used for estimating risks to their predators.

The characteristics of the ecosystem and receptors must be considered to reach appropriate conclusions about exposure. Abiotic attributes may increase or decrease the amount of a stressor contacted by receptors. For example, the presence of naturally anoxic areas above contaminated sediments in an estuary may reduce the amount of time that bottom-feeding fish spend in contact with the contaminated sediments and thereby reduce exposure to the contamination. Biotic interactions can also influence exposure. For example, competition for high-quality resources may force some organisms to utilize disturbed areas. The interaction between exposure and receptor behavior can influence both the initial and subsequent exposures. For example, some chemicals reduce the prey's ability to escape predators and thereby may increase predator exposure to the chemical as well as the prey's risk of predation. Alternatively, organisms may avoid areas, food, or water with contamination they can detect. While avoidance can reduce exposure to chemicals, it may increase other risks by altering habitat usage or other behavior.

Three dimensions must be considered when estimating exposure: intensity, time, and space. Intensity is the most familiar dimension for chemical and biological stressors and may be expressed as the amount of chemical contacted per day or the number of pathogenic organisms per unit area.

The temporal dimension of exposure has aspects of duration, frequency, and timing. Duration can be expressed as the time over which exposure occurs, exceeds some threshold intensity, or over which intensity is integrated. If exposure occurs as repeated, discrete events of about the same duration (e.g., floods), frequency is the important temporal dimension of exposure. If the repeated events have significant and variable durations, both duration and frequency must be considered. In addition, the timing of exposure, including the order or sequence of events, can be an important factor to describe. For example, in the Northeast, lakes receive high concentrations of hydrogen ions and aluminum during snow melt; this period also corresponds to the sensitive life stages of some aquatic organisms.

In chemical assessments, the dimensions of intensity and time are often combined by averaging intensity over time. The duration over which intensity is averaged is determined by considering both the ecological effects of concern and the likely pattern of exposure. For example, an assessment of bird kills associated with granular carbofuran focused on short-term exposures because the effect of concern was acute lethality (Houseknecht, 1993). Because toxicological tests are usually conducted using constant exposures, the most realistic comparisons between exposure and effects are made when exposure in the real world does not vary substantially. In these cases, the arithmetic average exposure over the time period of toxicological significance is the appropriate statistic to use (U.S. EPA, 1992d). However, as concentrations or contact rates become more episodic or variable, the arithmetic average may not reflect the toxicologically significant aspect of the exposure pattern. In extreme cases, averaging may not be appropriate at all, and assessors may need to use a toxic dynamic model to assess chronic effects.

Spatial extent is another dimension of exposure. It is most commonly expressed in terms of area (e.g., hectares of filled wetland, square meters that exceed a particular chemical threshold). At larger spatial scales, however, the shape or arrangement of exposure may be an important issue, and area alone may not be the appropriate descriptor of spatial extent for risk assessment. A general solution to the problem of incorporating pattern into ecological assessments has yet to be developed; however, the emerging field of landscape ecology and the increased availability of geographic information systems have greatly expanded the options for analyzing and presenting the spatial dimension of exposure.

This step completes exposure analysis. Exposure should be described in terms of intensity, space, and time, in units that can be combined with the effects assessment. In addition, the assessor should be able to trace the paths of stressors from the source to the receptors, completing the exposure pathway. The results of exposure analysis are summarized in the exposure profile, which is discussed in the next section.

4.2.2. Exposure Profile

The final product of exposure analysis is a summary profile of what has been learned. Depending on the risk assessment, the profile may be a written document, or a module of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated. In addition, compiling the exposure profile provides an opportunity to verify that the important exposure pathways identified in the conceptual model were evaluated.

The exposure profile identifies the receptor and describes the exposure pathways and intensity and spatial and temporal extent of co-occurrence or contact. It also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur (text note 4–11).

The profile should describe the relevant exposure pathways. If exposure can occur through many pathways, it may be useful to rank them, perhaps by contribution to total exposure. For example, consider an assessment of risks to grebes feeding on a mercury-contaminated lake. The grebes may be exposed to methyl mercury in fish that originated from historically contaminated sediments. They may also be exposed by drinking lake water, but comparing the two exposure pathways may show that the fish pathway contributes the vast majority of exposure to mercury.

The profile should describe the ecological entity that is exposed and represented by the exposure estimates described below. For example, the exposure profile may focus on the local population of grebes feeding on a specific lake during the summer months.

The assessor should state how each of the three general dimensions of exposure (intensity, time, and space) was treated and why that treatment is necessary or appropriate. Continuing with the grebe example, exposure might be expressed as the daily potential dose averaged over the summer months and over the extent of the lake.

The profile should also describe how variability in receptor attributes or stressor levels can change exposure. For example, variability in receptor attributes of the grebes may be addressed by using data on how the proportion of fish in the diet varies among individuals. If several lakes were the subject of the assessment and individual grebes tended to feed on the same lake throughout the season, variability in stressor levels could be addressed by comparing exposures among the lakes.

Variability can be described by using a distribution or by describing where a point estimate is expected to fall on a distribution. Cumulative-distribution functions (CDFs) and probability-density functions (PDFs) are two common presentation formats; (see Appendix B, figures B1 and B2). Figures 5–4 to 5–6 show examples of cumulative frequency plots of exposure data. The point estimate/descriptor approach is used when there is not enough information to describe a distribution. We recommend using the descriptors discussed in U.S. EPA, 1992d, including central tendency to refer to the mean or median of the distribution, high end to refer to exposure estimates that are expected to fall between the 90th and 99.9th percentile of the exposure distribution, and bounding estimates to refer to those higher than any actual exposure.

The exposure profile should summarize important uncertainties (i.e., lack of knowledge) (see section 4.1.3 for a discussion of the different sources of uncertainty). In particular, the assessor should:

- Identify key assumptions and describe how they were handled.
- Discuss (and quantify if possible) the magnitude of sampling and/or measurement error.
- Identify the most sensitive variables influencing exposure.
- Identify which uncertainties can be reduced through the collection of more data.

Uncertainty about a quantity's true value can be shown by calculating error bounds on a point estimate, as shown in figure 5–2.

All of the above information is synthesized to reach a conclusion about the likelihood that exposure will occur. The exposure profile is one of the products of the analysis phase. It is combined with the stressor-response profile (the product of the ecological effects characterization discussed in the next section) during risk characterization.

4.3. Characterization of Ecological Effects

Characterization of ecological effects describes the effects that are elicited by a stressor, links these effects with the assessment endpoints, and evaluates how the effects change with varying stressor levels. Ecological effects characterization begins by evaluating effects data (discussed generally in section 4.1) to further specify the effects that are elicited, confirm that the effects are consistent with the assessment endpoints, and confirm that the conditions under which they occur are consistent with the conceptual model. Once the effects of interest are identified, then an ecological response analysis (section 4.3.1) is conducted to evaluate how the magnitude of the effects change with varying stressor levels, evaluate the evidence that the stressor causes the effect, and link the effects with the assessment endpoint. The conclusions of the ecological effects characterization are summarized in a stressor-response profile (section 4.3.2).

4.3.1. Ecological Response Analysis

Ecological response analysis has three primary elements: determining the relationship between stressor levels and ecological effects (section 4.3.1.1), evaluating the plausibility that effects may occur or are occurring as a result of exposure to stressors (section 4.3.1.2), and linking measurable ecological effects with the assessment endpoints when assessment endpoints cannot be directly measured (section 4.3.1.3).

4.3.1.1. Stressor-Response Analysis

Evaluating ecological risks requires an understanding of the relationships between stressor levels and resulting ecological responses. The stressor-response relationships used in a particular assessment depend on the scope and nature of the ecological risk assessment as defined in problem formulation and reflected in the analysis plan. For example, an assessor may need a point estimate of an effect (such as an LC_{50}) to compare with point estimates from other stressors. The shape of the stressor-response curve may be critical for determining the presence or absence of an effects threshold or for evaluating incremental risks, or stressor-response curves may be used as input for ecological effects models. If sufficient data are available, the risk assessor may construct cumulative distribution functions using multiple point estimates of effects. Or the assessor may use process models that already incorporate empirically derived stressor-response relationships (section 4.3.1.3). Some questions for stressor-response analysis are provided in text note 4–12.

This section describes a range of stressor-response approaches available to risk assessors following a theme of variations on the classical stressor-response relationship (e.g., figure 4–2). While quantifying this relationship is encouraged, qualitative stressor-response evaluations are also possible (text note 4–13). In addition, many stressor-response relationships are more complex than the simple curve shown in this figure. Ecological systems frequently show responses to stressors that may involve abrupt shifts to new community or system types (Holling, 1978).

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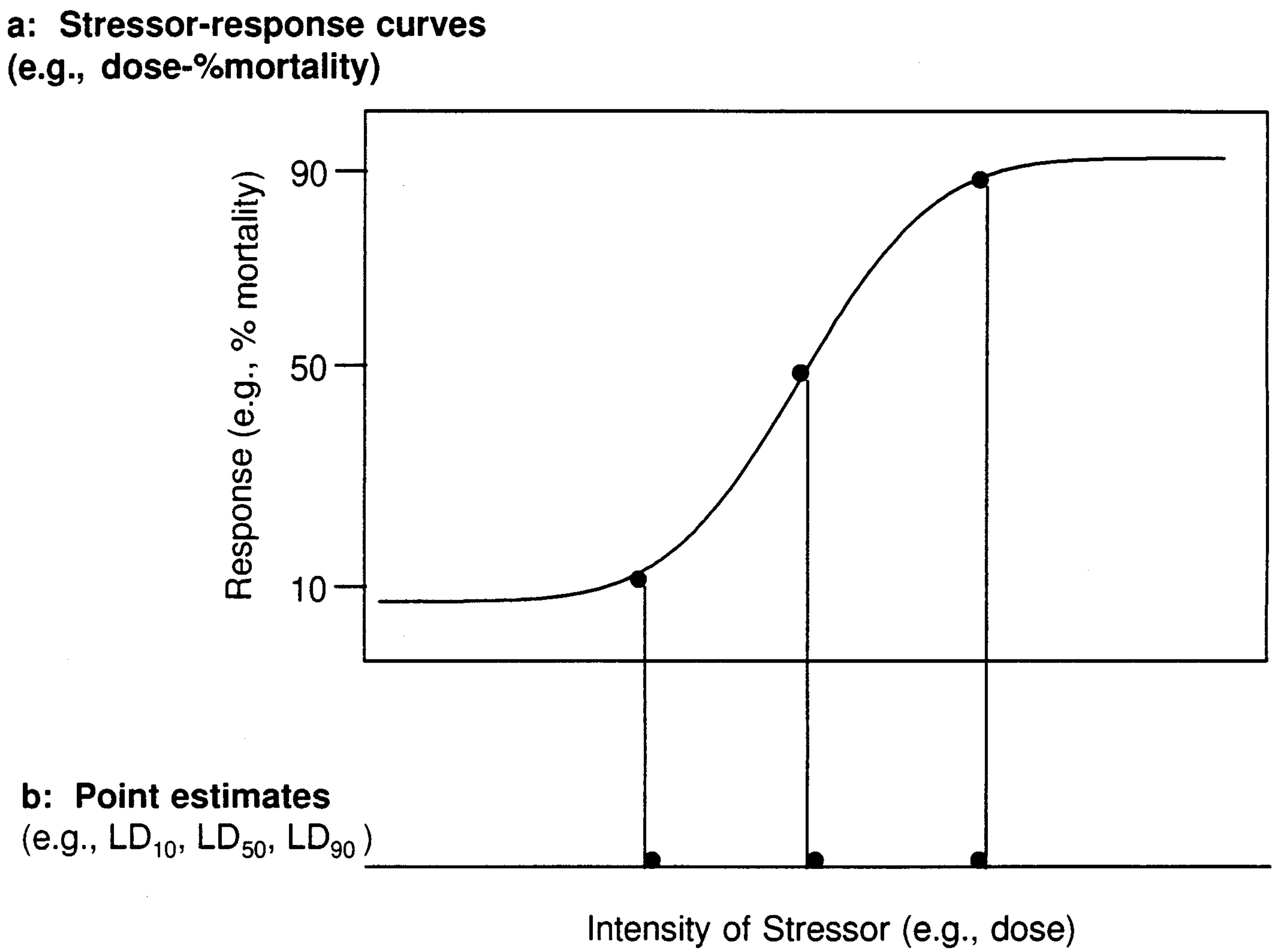

Figure 4-2. A simple example of a stressor-response relationship.

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In simple cases, the response will be one variable (e.g., mortality, incidence of abnormalities), and most quantitative techniques have been developed for univariate analysis. If the response of interest is composed of many individual variables (e.g., species abundances in an aquatic community), multivariate statistical techniques may be useful. These techniques have a long history of use in ecology (see texts by Gauch, 1982; Pielou, 1984; Ludwig and Reynolds, 1988) but have not yet been extensively applied in risk assessment.

Stressor-response relationships can be described using any of the dimensions of exposure (i.e., intensity, time, or space). Intensity is probably the most familiar dimension and is often used for chemicals (e.g., dose, concentration). The duration of exposure is also commonly used for chemical stressor-response relationships; for example, median acute effects levels are always associated with a time parameter (e.g., 24 hr, 48 hr, 96 hr). As noted in text note 4–13, the timing of exposure was the critical dimension in evaluating the relationship between seed germination and flooding (Pearlstine et al., 1985). The spatial dimension is often of concern for physical stressors. For example, the spatial extent of suitable habitat was related to the probability of sighting a spotted owl (Thomas et al., 1990), and water-table depth was related to the growth of tree species by Phipps (1979).

Single-point estimates and stressor-response curves can be generated for some biological stressors. For pathogens such as bacteria and fungi, inoculum levels (e.g., spores per ml; propagules per unit of substrate) may be related to the level of symptoms in a host (e.g., lesions per area of leaf surface, total number of plants infected) or actual signs of the pathogen (asexual or sexual fruiting bodies, sclerotia, etc.). For other biological stressors such as introduced species, developing simple stressor-response relationships may be inappropriate.

Data from individual experiments can be used to develop curves and point estimates both with and without associated uncertainty estimates (see figures 5–2 and 5–3). The advantages of curve-fitting approaches include using all of the available experimental data and the ability to interpolate to values other than the data points measured. If extrapolation outside the range of experimental data is required, risk assessors should justify that the observed experimental relationships remain valid. A disadvantage of curve fitting is that the number of data points required to complete an analysis may not always be available. For example, while standard toxicity tests with aquatic organisms frequently contain sufficient experimental treatments to permit regression analysis, frequently this is not the case for toxicity tests with wildlife species.

Risk assessors sometimes use curve-fitting analyses to determine particular levels of effect for evaluation. These point estimates are interpolated from the fitted line. Point estimates may be adequate for simple assessments or comparative studies of risk and are also useful if a decision rule for the assessment was identified during the planning phase (see section 2). Median effect levels (text note 4–14) are frequently selected because the level of uncertainty is minimized at the midpoint of the regression curve. While a 50% effect for an endpoint such as survival may not be appropriately protective for the assessment endpoint, median effect levels can be used for preliminary assessments or comparative purposes, especially when used in combination with uncertainty modifying factors (see text note 5–2). Selection of a different effect level (10%, 20%, etc.) can be arbitrary unless there is some clearly defined benchmark for the assessment endpoint. Thus, it is preferable to carry several levels of effect or the entire stressor-response curve forward to risk estimation.

When risk assessors are particularly interested in effects at lower stressor levels, they may seek to establish ''no-effect'' levels of a stressor based on comparisons between experimental treatments and controls. Statistical hypothesis testing is frequently used for this purpose. (Note that statistical hypotheses are different from the risk hypotheses discussed in problem formulation; see text note 3–10). An example of this approach for deriving chemical no-effect levels is provided in text note 4–15. An advantage of statistical hypothesis testing is that the risk assessor is not required to pick a particular effect level of concern. The no-effect level is determined instead by experimental conditions such as the number of replicates as well as the variability inherent in the data. Thus it is important to consider the level of effect detectable in the experiment (i.e., its power) in addition to reporting the no-effect level. Another drawback of this approach is that it is difficult to evaluate effects associated with stressor levels other than the actual treatments tested. Several investigators (Stephan and Rogers, 1985; Suter, 1993a) have proposed using regression analysis as an alternative to statistical hypothesis testing.

In observational field studies, statistical hypothesis testing is often used to compare site conditions with a reference site(s). The difficulties of drawing proper conclusions from these types of studies (which frequently cannot employ replication) have been discussed by many investigators, including Hurlbert (1984), Stewart-Oaten et al. (1986), Wiens and Parker (1995), and Eberhardt and Thomas (1991). Risk assessors should examine whether sites were carefully matched to minimize differences other than the stressor and consider whether potential covariates should be included in any analysis. An advantage of experimental field studies is that treatments can be replicated, increasing the confidence that observed differences are due to the treatment.

Data available from multiple experiments can be used to generate multiple point estimates that can be displayed as cumulative distribution functions. Figure 5–6 shows an example of a cumulative distribution function for species sensitivity derived from multiple point estimates (EC5s) for freshwater algae exposed to a herbicide. These distributions facilitate identification of stressor levels that affect a minority or majority of species. A limiting factor in the use of cumulative frequency distributions is the amount of data needed as input. Cumulative effects distribution functions can also be derived from models that use Monte Carlo or other methods to generate distributions based on measured or estimated variation in input parameters for the models.

When multiple stressors are present, stressor-response analysis is particularly challenging. Stressor-response relationships can be constructed for each stressor separately and then combined. Alternatively, the relationship between response and the suite of stressors can be combined in one analysis. It is preferable to directly evaluate complex chemical mixtures present in environmental media (e.g., wastewater effluents, contaminated soils; U.S. EPA, 1986b), but it is important to consider the relationship between the samples tested and the potential spatial and temporal variability in the mixture. The approach taken for multiple stressors depends on the feasibility of measuring the suite of stressors and whether an objective of the assessment is to project different stressor combinations.

In some cases, multiple regression analysis can be used to empirically relate multiple stressors and a response. Detenbeck (1994) used this approach to evaluate change in the water quality of wetlands resulting from multiple physical stressors. Multiple regression analysis can be difficult to interpret if the explanatory variables (i.e., the stressors) are not independent. Principal components analysis can be used to extract independent explanatory variables formed from linear combinations of the original variables (Pielou, 1984).

4.3.1.2. Establishing Cause and Effect Relationships (Causality)

Causality is the relationship between cause (one or more stressors) and effect (assessment endpoint response to one or more stressors). Without a sound basis for linking cause and effect, uncertainty in the conclusions of an ecological risk assessment is likely to be high. Developing causal relationships is especially important for risk assessments driven by observed adverse ecological effects such as bird or fish kills or a shift in the species composition of an area. This section proposes considerations for evaluating causality based on criteria primarily for observational data developed by Fox (1991) and additional criteria for experimental evaluation of causality modified from Koch's postulates (e.g. see Woodman and Cowling, 1987).

Evidence of causality may be derived from observational evidence (e.g., bird kills are associated with field application of a pesticide) or experimental data (e.g., laboratory tests with the pesticides in question show bird kills at levels similar to those found in the field), and causal associations can be strengthened when both types of information are available. But since not all situations lend themselves to formal experimentation, scientists have looked for other criteria, based largely on observation rather than experiment, to support a plausible argument for cause and effect. Text note 4–16 provides criteria based on Fox (1991) that are very similar to others reviewed by Fox (U.S. Department of Health, Education, and Welfare, 1964; Hill, 1965; Susser, 1986a,b). While data to support some criteria may be incomplete or missing for any given assessment, these criteria offer a useful way of evaluating available information.

The strength of association between stressor and response is often the main reason that adverse effects (such as bird kills) are first noticed. A stronger response to a hypothesized cause is more likely to indicate true causation. Additional strong evidence of causation is when a response follows after a change in the hypothesized cause (predictive performance).

The presence of a biological gradient or stressor-response relationship is another important criterion for causality. The stressor-response relationship need not be linear. It can be a threshold, sigmoidal, or parabolic phenomenon, but in any case it is important that it can be demonstrated. Biological gradients, such as decreasing effects downstream of a toxic discharge, are frequently used as evidence of causality. To be credible, such relationships should be consistent with current biological or ecological knowledge (biological plausibility).

A cause-effect relationship that is demonstrated repeatedly (consistency of association) provides strong evidence of causality. Consistency may be shown by a greater number of instances of association between stressor and response, occurrences in diverse ecological systems, or associations demonstrated by diverse methods (Hill, 1965). Fox (1991) adds that in ecoepidemiology the occurrence of an association in more than one species and species population is very strong evidence for causation. An example would be the numerous species of birds that were killed as a result of carbofuran application (Houseknecht, 1993). Fox (1991) also believes that causality is supported if the same incident is observed by different persons under different circumstances and at different times.

Conversely, inconsistency in association between stressor and response is strong evidence against causality (e.g., the stressor is present without the expected effect, or the effect occurs but the stressor is not found). Temporal incompatibility (i.e., the presumed cause does not precede the effect) and incompatibility with experimental or observational evidence (factual implausibility) are also indications against a causal relationship.

Two other criteria may be of some help in defining causal relationships: specificity of an association and probability. The more specific the effect, the more likely it is to have a consistent cause. However, Fox (1991) argues that effect specificity does little to strengthen a causal claim. Disease can have multiple causes, a substance can behave differently in different environments or cause several different effects, and biochemical events may result in a diverse array of biological responses. But in general, the more specific or localized the effects, the easier it is to identify the cause. Sometimes, a stressor may have a distinctive mode of action that suggests its role. Yoder and Rankin (1995) found that patterns of change observed in fish and benthic invertebrate communities could serve as indicators for different types of anthropogenic impact (e.g., nutrient enrichment vs. toxicity).

For some pathogenic biological stressors, the causal evaluations proposed by Koch (text note 4–17) may be useful. For chemicals, ecotoxicologists have slightly modified Koch's postulates to provide evidence of causality (Adams, 1963; Woodman and Cowling, 1987). The modifications are:

- The injury, dysfunction, or other putative effect of the toxicant must be regularly associated with exposure to the toxicant and any contributory causal factors.
- Indicators of exposure to the toxicant must be found in the affected organisms.
- The toxic effects must be seen when normal organisms or communities are exposed to the toxicant under controlled conditions, and any contributory factors should be manifested in the same way during controlled exposures.
- The same indicators of exposure and effects must be identified in the controlled exposures as in the field.

These modifications are conceptually identical to Koch's postulates. While useful, this approach may not be practical if resources for experimentation are not available or if an adverse effect may be occurring over such a wide spatial extent that experimentation and correlation may prove difficult or yield equivocal results.

Experimental techniques are frequently used for evaluating causality in complex chemical mixtures. Options include evaluating separated components of the mixture, developing and testing a synthetic mixture, or determining how the toxicity of a mixture relates to the toxicity of individual components. The choice of method depends on the goal of the assessment and the resources and test data that are available.

Laboratory toxicity identification evaluations (TIEs) can be used to help determine which components of a chemical mixture are causing toxic effects. By using fractionation and other methods, the TIE approach can help identify chemicals responsible for toxicity and show the relative contributions to toxicity of different chemicals in aqueous effluents (U.S. EPA, 1988a, 1989b, c) and sediments (e.g., Ankley et al., 1990).

Risk assessors may utilize data from synthetic chemical mixtures if the individual chemical components are well characterized. This approach allows for manipulation of the mixture and investigation of how varying the components that are present or their ratios may affect mixture toxicity but also requires additional assumptions about the relationship between effects of the synthetic mixture and those of the environmental mixture.

When the modes of action of chemicals in a mixture are known to be similar, an additive model has been successful in predicting combined effects (Könemann, 1981; Hermens et al., 1984a; McCarty and Mackay, 1993; Sawyer and Safe, 1985; Broderius et al., 1995). In this situation, the contribution of each chemical to the overall toxicity of the mixture can be evaluated. However, the situation is more complicated when the modes of action of the chemical constituents are unknown or partially known (see additional discussion in section 5.1.2).

4.3.1.3. Linking Measures of Effect to Assessment Endpoints

Assessment endpoints express the environmental values of concern for a risk assessment, but they cannot always be measured directly. When measures of effect differ from assessment endpoints, sound and explicit linkages between the two are needed. Risk assessors may make these linkages in the analysis phase or, especially when linkages rely on expert judgment, risk assessors may work with measures of effect through risk estimation (in risk characterization) and then make the connection with the assessment endpoints. Common extrapolations used to link measures of effect with assessment endpoints are shown in text note 4–18.

General Considerations. During the preparation of the analysis plan in problem formulation, risk assessors identify the extrapolations required between assessment endpoints and measures of effect. During the analysis phase, risk assessors should revisit the questions listed in text note 4–19 before proceeding with specific extrapolation approaches to use.

The scope and nature of the risk assessment and the environmental decision to be made help determine the degree of uncertainty (and type of extrapolation) that is acceptable. At an early stage of a tiered risk assessment, extrapolations from minimal data that involve large uncertainties are acceptable when the primary purpose is to determine whether a risk exists given worst-case exposure and effects scenarios. To define risk further at later stages of the assessment, additional data and more sophisticated extrapolation approaches are usually required.

The scope of the risk assessment also influences extrapolation through the nature of the assessment endpoint. Preliminary assessments that evaluate risks to general trophic levels, such as fish and birds, may extrapolate among different genera or families to obtain a range of sensitivity to the stressor. On the other hand, assessments concerned with management strategies for a particular species may employ population models.

Analysis phase activities may suggest additional extrapolation needs. Evaluation of exposure may indicate different spatial or temporal scales than originally anticipated. If spatial scales are broadened, additional receptors may need to be included in extrapolation models. If a stressor persists for an extended time in the environment, it may be necessary to extrapolate short-term responses over a longer period of exposure, and population level effects may become more important.

Whatever methods are employed to link assessment endpoints with measures of effect, it is important to apply the methods in a manner consistent with sound ecological principles and the availability of an appropriate database. For example, it is inappropriate to use structure-activity relationships to predict toxicity from chemical structure unless the chemical under consideration has a similar mode of toxic action to the reference chemicals (Bradbury, 1994). Similarly, extrapolations from upland avian species to waterfowl may be more credible if factors such as differences in food preferences, body mass, physiology, and seasonal behavior (e.g., mating and migration habits) are considered. Extrapolations made in a rote manner or that are biologically implausible will erode the overall credibility of the assessment.

Finally, many extrapolation methods are limited by the availability of suitable databases. Although these databases are generally largest for chemical stressors and aquatic species, data do not exist for all taxa or effects. Chemical effects databases for mammals, amphibians, or reptiles are extremely limited, and there is even less information on most biological and physical stressors. Risk assessors should be aware that extrapolations and models are only as useful as the data on which they are based and should recognize the great uncertainties associated with extrapolations that lack an adequate empirical or process-based rationale.

The rest of this section addresses the approaches used by risk assessors to link measures of effect to assessment endpoints, as noted below.

- Linkages based on expert judgment. This approach is not as desirable as empirical or process-based approaches, but is the only option when data are lacking.
- Linkages based on empirical or process models. Empirical extrapolations use experimental or observational data that may or may not be organized into a database. Process-based approaches are based on some level of understanding of the underlying operations of the system under consideration.

Judgment Approaches for Linking Measures of Effect to Assessment Endpoints. Expert judgment approaches rely on the professional expertise of risk assessors, expert panels, or others to relate changes in measures of effect to changes in the assessment endpoint. They are essential when databases are inadequate to support empirical models and process models are unavailable or inappropriate. Expert judgment linkages between measures of effect and assessment endpoints can be just as credible as empirical or process-based expressions, provided they have a sound scientific basis. This section highlights expert judgment extrapolations between species, from laboratory data to field effects, and between geographic areas.

Because of the uncertainties in predicting the effects of biological stressors such as introduced species, expert judgment approaches are commonly used. For example, there may be measures of effect data on a foreign pathogen that attacks a certain tree species not found in the United States, but the assessment endpoint concerns the survival of a commercially important tree found only in the United States. In this case, a careful evaluation and comparison of the life history and environmental requirements of both the pathogen and the two tree species may contribute toward a useful determination of potential effects, even though the uncertainty may be high. Expert panels are typically used for this kind of evaluation (USDA, 1993).

Risks to organisms in field situations are best estimated from studies at the site of interest. However, such data are not always available. Frequently, risk assessors must extrapolate from laboratory toxicity test data to field effects. Text note 4–20 summarizes some of the considerations for risk assessors when extrapolating from laboratory toxicity test results to field situations for chemical stressors. Factors altering exposure in the field are among the most important factors limiting extrapolations from laboratory test results, but indirect effects on exposed organisms due to predation, competition, or other biotic or abiotic factors not evaluated in the laboratory may also be significant. Variations in direct chemical effects between laboratory tests and field situations may not contribute as much to the overall uncertainty of the extrapolation.

In addition to single-species tests, laboratory multiple species tests are sometimes used to predict field effects. While these tests have the advantage of evaluating some aspects of a real ecological system, they also have inherent scale limitations (e.g., lack of top trophic levels) and may not adequately represent features of the field system important to the assessment endpoint.

Extrapolations based on expert judgment are frequently required when assessors wish to use field data obtained from one geographic area and apply them to a different area of concern, or to extrapolate from the results of laboratory tests to more than one geographic region. In either case, risk assessors should consider variations between regions in environmental conditions, spatial scales and heterogeneities, and ecological forcing functions (see below).

Variations in environmental conditions in different geographic regions may alter stressor exposure and effects. If exposure to chemical stressors can be accurately estimated and are expected to be similar (e.g., see text note 4–20), the same species in different areas may respond similarly. For example, if the pesticide granular carbofuran were applied at comparable rates throughout the country, seed-eating birds could be expected to be similarly affected by the pesticide (Houseknecht, 1993). Nevertheless, the influence of environmental conditions on stressor exposure and effects can be substantial.

For biological stressors, environmental conditions such as climate, habitat, and suitable hosts play major roles in determining whether a biological stressor becomes established. For example, climate would prevent establishment of the Mediterranean fruit fly in the much colder northeastern United States. Thus, a thorough evaluation of environmental conditions in the area versus the natural habitat of the stressor is important. Even so, many biological stressors can adapt readily to varying environmental conditions, and the absence of natural predators or diseases may play an even more important role than abiotic environmental conditions.

For physical stressors that have natural counterparts, such as fire, flooding, or temperature variations, effects may depend on the natural variations in these parameters for a particular region. Thus, the comparability of two regions depends on both the pattern and range of natural disturbances.

Spatial scales and heterogeneities affect comparability between regions. Effects observed over a large scale may be difficult to extrapolate from one geographical location to another mainly because the spatial heterogeneity is likely to differ. Factors such as number and size of land-cover patches, distance between patches, connectivity and conductivity of patches (e.g., migration routes), and patch shape may be important. Extrapolations can be facilitated by using appropriate reference sites, such as sites in comparable ecoregions (Hughes, 1995).

Ecological forcing functions may differ between geographic regions. Forcing functions are critical abiotic variables that exert a major influence on the structure and function of ecological systems. Examples include temperature fluctuations, fire frequency, light intensity, and hydrologic regime. If these differ significantly between sites, it may be inappropriate to extrapolate stressor effects from one system to another.

The following references may be useful when assessing effects over different geographical areas: Bedford and Preston (1988), Detenbeck et al. (1992), Gibbs (1993), Gilbert (1987), Gosselink et al. (1990), Preston and Bedford (1988), and Risser (1988).

Empirical and Process-Based Approaches for Linking Measures of Effect to Assessment Endpoints. There are a variety of empirical and process-based approaches available to risk assessors depending on the scope of the assessment and the data and resources available. Empirical and process-based approaches include numerical extrapolations between effects measures and assessment endpoints. These linkages range in sophistication from applying an uncertainty factor to using a complex model requiring extensive measures of effects and measures of ecosystem and receptor characteristics as input. But even the most sophisticated quantitative models involve qualitative elements and assumptions and thus require professional judgment for evaluation. Individuals who use models and interpret their results should be familiar with the underlying assumptions and components contained in the model.

Empirical Approaches. Empirically based uncertainty factors or taxonomic extrapolations may be used when adequate effects databases are available but the understanding of underlying mechanisms of action or ecological principles is limited. When sufficient information on stressors and receptors is available, process-based approaches such as pharmacokinetic/pharmacodynamic models or population or ecosystem process models may be used. Regardless of the options used, risk assessors should justify and adequately document the approach selected.

Uncertainty factors are used to ensure that effects measures are sufficiently protective of assessment endpoints. Uncertainty factors are empirically derived numbers that are divided into measure of effects values to give an estimated stressor level that should not cause adverse effects to the assessment endpoint. Uncertainty factors have mostly been developed for chemicals because of the extensive ecotoxicologic databases available, especially for aquatic organisms. Uncertainty factors are useful when decisions must be made about stressors in a short time and with little information.

Uncertainty factors have been used to compensate for assessment endpoint/effect measures differences between endpoints (acute to chronic effects), between species, and between test situations (e.g., laboratory to field). Typically, uncertainty factors vary inversely with the quantity and type of effects measures data available (Zeeman, 1995). Uncertainty factors have been used in screening-level assessments of new chemicals (Nabholz, 1991), in assessing the risks of pesticides to aquatic and terrestrial organisms (Urban and Cook, 1986), and in developing benchmark dose levels for human health effects (U.S. EPA, 1995d).

In spite of their usefulness, uncertainty factors can also be misused, especially when used in an overly conservative fashion, as when chains of factors are multiplied together without sufficient justification. Like other approaches to bridging data gaps, uncertainty factors are often based on a combination of scientific analysis, scientific judgement and policy judgement (see section 4.1.3). It is important to differentiate among these three elements when documenting the basis for the uncertainty factors used.

Empirical data can be used to facilitate extrapolations between species to species, genera, families, or orders or functional groups (e.g., feeding guilds) (Suter, 1993a). Suter et al. (1983), Suter (1993a), and Barnthouse et al. (1987, 1990) developed methods to extrapolate toxicity among freshwater and marine fish and arthropods. As noted by Suter

(1993a), the uncertainties associated with extrapolating between orders, classes, and phyla tend to be very high. However, extrapolations can be made with fair certainty between aquatic species within genera and genera within families. Further applications of this approach (e.g., for chemical stressors and terrestrial organisms) are limited by a lack of suitable databases.

Dose-scaling or allometric regression has also been used to extrapolate the effects of a chemical stressor to another species. The method is used for human health risk assessment but has not been applied extensively to ecological effects (Suter, 1993a).

Allometric regression has been used with avian species (Kenaga, 1973) and to a limited extent for estimating effects to marine organisms based on their length. For chemical stressors, allometric relationships can enable an assessor to estimate toxic effects to species not commonly tested, such as native mammalian species. It is important that the assessor consider the taxonomic relationship between the known species and the species of interest. The closer the two are related, the more likely that the toxic response will be similar. Allometric approaches should not be applied to species that differ greatly in uptake, metabolism, or depuration of a chemical.

Process-Based Approaches. Process models for extrapolation are representations or abstractions of a system or process (Starfield and Bleloch, 1991) that incorporate causal relationships and provide a predictive capability that does not depend on the availability of existing stressor-response information as empirical models do (Wiegert and Bartell, 1994). Process models enable assessors to translate data on individual effects (e.g., mortality, growth, and reproduction) to potential alterations in specific populations, communities, or ecosystems. Such models can be used to evaluate risk hypotheses about the duration and severity of a stressor on an assessment endpoint that cannot be tested readily in the laboratory.

There are two major types of models: single-species population models and multispecies community and ecosystem models. Population models describe the dynamics of a finite group of individuals through time and have been used extensively in ecology and fisheries management and to assess the impacts of power plants and toxicants on specific fish populations (Barnthouse et al., 1987; Barnthouse et al., 1990). Population models are useful in answering questions related to short- or long-term changes of population size and structure and can be used to estimate the probability that a population will decline below or grow above a specified abundance (Ginzburg et al., 1982; Ferson et al., 1989). This latter application may be useful when assessing risks associated with biological stressors such as introduced or pest species. Excellent reviews of population models are presented by Barnthouse et al. (1986) and Wiegert and Bartell (1994). Emlen (1989) has reviewed population models that can be used for terrestrial risk assessment.

Proper use of the population models requires a thorough understanding of the natural history of the species under consideration, as well as knowledge of how the stressor influences its biology. Model input can include somatic growth rates, physiological rates, fecundity, survival rates of various classes within the population, and how these change when the population is exposed to the stressor and other environmental factors. In addition, the effects of population density on these parameters may be important (Hassell, 1986) and should be considered in the analysis of uncertainty.

Community and ecosystem models (e.g., Bartell et al., 1992; O'Neill et al., 1982) are particularly useful when the assessment endpoint involves structural (e.g., community composition) or functional (e.g., primary production) elements of the system potentially at risk. These models can also be useful when secondary effects are of concern. Changes in various community or ecosystem components such as populations, functional types, feeding guilds, or environmental processes can be estimated. By incorporating submodels describing the dynamics of individual system components, these models permit evaluation of risk to multiple assessment endpoints within the context of the larger environmental system.

Risk assessors should evaluate the degree of aggregation in population or multispecies model parameters that is appropriate based both on the input data available and on the desired output of the model. For example, if a decision is required about a particular species, a model that lumps species into trophic levels or feeding guilds will not be very useful. Assumptions concerning aggregation in model parameters should be included in the discussion of uncertainty.

4.3.2. Stressor-Response Profile

The final product of ecological response analysis is a summary profile of what has been learned. Depending on the risk assessment, the profile may be a written document, or a module of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated. A useful approach in preparing the stressor-response profile is to imagine that it will be used by someone else to perform the risk characterization. Using this approach, the assessor may be better able to extract the information most important to the risk characterization phase. In addition, compiling the stressor-response profile provides an opportunity to verify that the assessment and measures of effect identified in the conceptual model were evaluated.

Risk assessors should address several questions in the stressor-response profile (text note 4–21). Depending on the type of risk assessment, affected ecological entities could include single species, populations, general trophic levels, communities, ecosystems, or landscapes. The nature of the effect(s) should be germane to the assessment endpoint(s). Thus if a single species is affected, the effects should represent parameters appropriate for that level of organization. Examples include effects on mortality, growth, and reproduction. Short- and long-term effects should be reported as appropriate. At the community level, effects could be summarized in terms of structure or function depending on the assessment endpoint. At the landscape level, there may be a suite of assessment endpoints and each should be addressed separately.

Examples of different approaches for displaying the intensity of effects as stressor-response curves or point estimates were provided in section 4.3.1.1. Other information such as the spatial area or time to recovery may be appropriate, depending on the scope of the assessment. Causal analyses are important, especially for assessments that include field observational data.

While ideally the stressor-response profile should express effects in terms of the assessment endpoint, this will not always be possible. Especially where it is necessary to use qualitative extrapolations between assessment endpoints and measures of effect, the stressor-response profile may only contain information on measures of effect. Under these circumstances, risk will be estimated using the measures of effects, and extrapolation to the assessment endpoints will occur during risk characterization.

Risk assessors need to be descriptive and candid about any uncertainties associated with the ecological response analysis. If it was necessary to extrapolate from measures of effect to the assessment endpoint, describe both the extrapolation and its basis. Similarly, if a benchmark or similar reference dose or concentration was calculated, discuss the extrapolations and uncertainties associated with its development. For additional information on establishing reference concentrations, see Nabholz (1991), Urban and Cook (1986), Stephan et al. (1985), Van Leeuwen et al. (1992), Wagner and L-kke (1991), and Okkerman et al. (1993). Finally, the assessor should clearly indicate major assumptions and default values used in models.

At the end of the analysis phase, the stressor-response and exposure profiles are used to estimate risks. These profiles provide the opportunity to review what has been learned and to summarize this information in the most useful format for risk characterization. Whatever form the profiles take, they ensure that the necessary information is available for risk characterization.

5. Risk Characterization

Risk characterization (figure 5–1) is the final phase of ecological risk assessment. Its goals are to use the results of the analysis phase to estimate risk to the assessment endpoints identified in problem formulation (section 5.1), interpret the risk estimate (section 5.2), and report the results (section 5.3).

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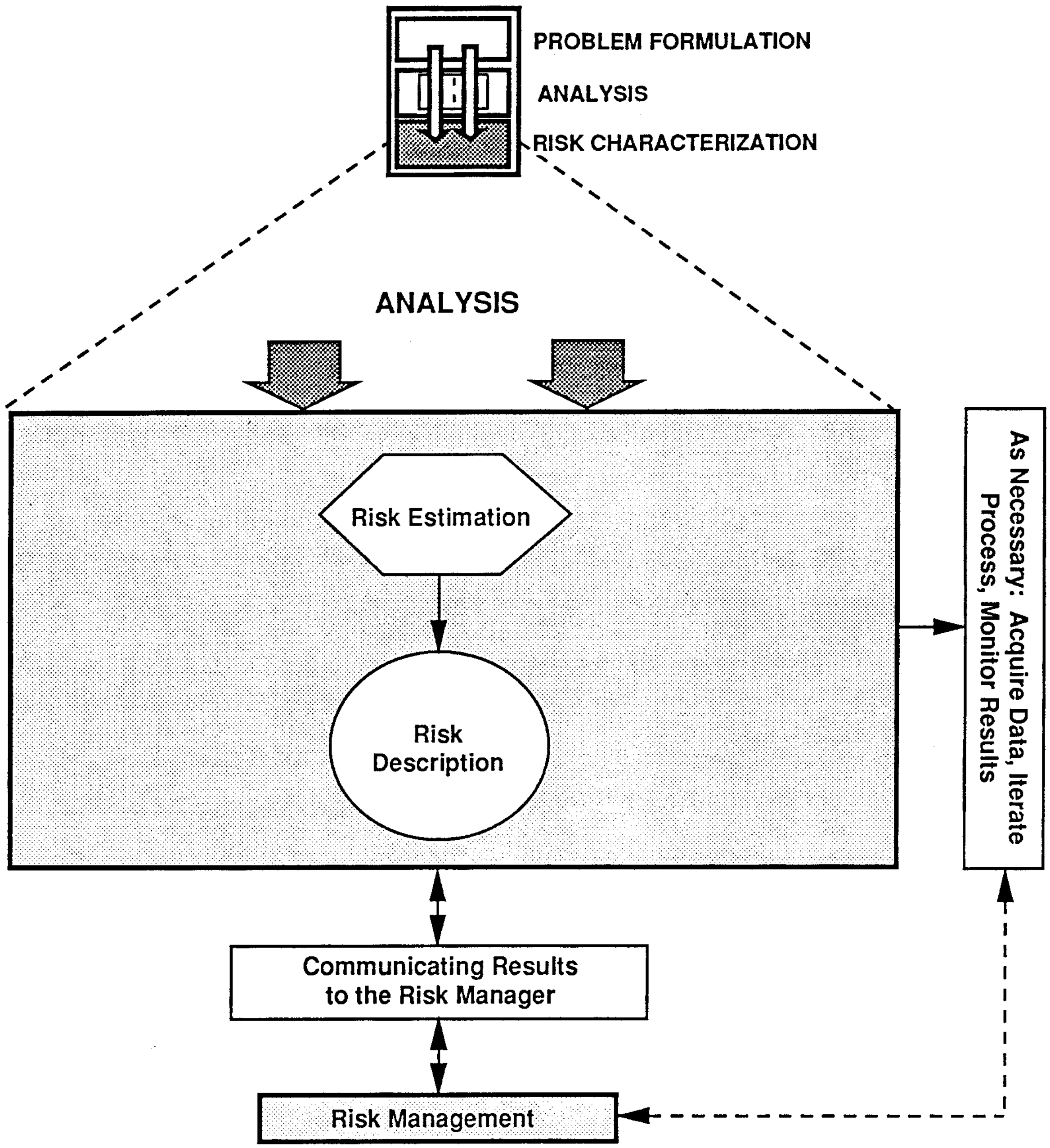

Figure 5-1. Risk characterization.

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Risk characterization is a major element of the risk assessment report. To be successful, it should provide clear information to the risk manager to use in environmental decision making (NRC, 1994; see section 6). If the risks are not sufficiently defined to support a management decision, the risk manager may elect to proceed with another iteration of the risk assessment process. Additional research or a monitoring program may improve the risk estimate or help to evaluate the consequences of a risk management decision.

5.1. Risk Estimation

Risk estimation determines the likelihood of adverse effects to assessment endpoints by integrating exposure and effects data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles which are developed according to the analysis plan (section 3.5). Risks can be estimated by one or more of the following approaches: (1) estimates expressed as qualitative categories, (2) estimates comparing single-point estimates of exposure and effects, (3) estimates incorporating the entire stressor-response relationship, (4) estimates incorporating variability in exposure and effects estimates, (5) estimates based on process models that rely partially or entirely on theoretical approximations of exposure and effects, and (6) estimates based on empirical approaches, including field observational data.

5.1.1. Risk Estimates Expressed as Qualitative Categories

In some cases, best professional judgment may be used to express risks qualitatively using categories such as low, medium, and high or yes and no. This approach is most frequently used when exposure and effects data are limited or not easily expressed in quantitative terms. A U.S. Forest Service assessment used qualitative categories because of limitations on both the exposure and effects data for the introduced species of concern as well as the resources available for the assessment. (text note 5–1)

5.1.2. Single-Point Estimates

When sufficient data are available to quantify exposure and effects estimates, the simplest approach for comparing the estimates is to use a ratio of two numbers (figure 5–2a). Typically, the ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration. Quotients are commonly used for chemical stressors, where reference or benchmark toxicity values are widely available (text note 5–2).

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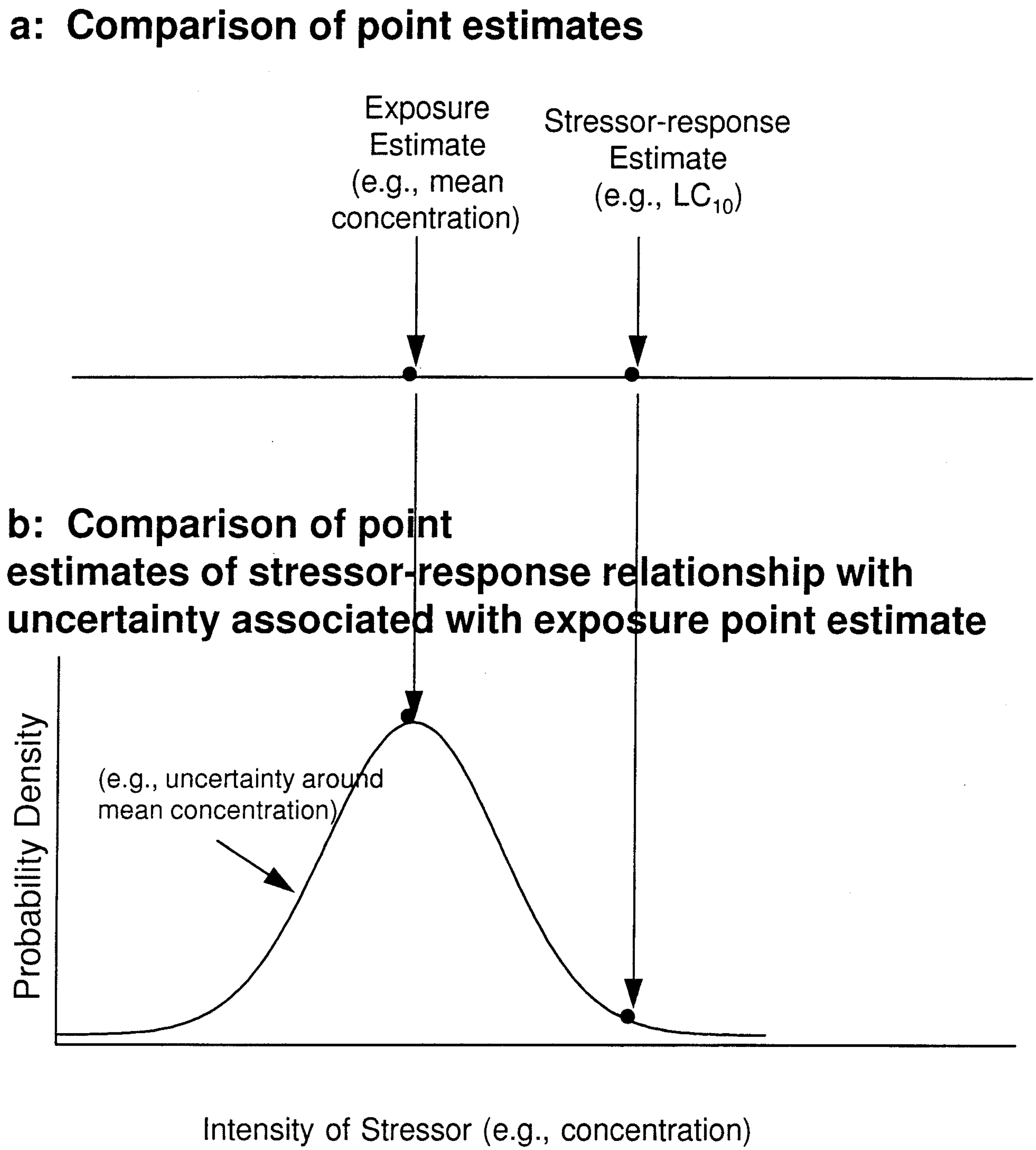

Figure 5-2. Risk estimation techniques. a. Comparison of exposure and stressor-response point estimates. b. Comparison of point estimates from the stressor-response relationship with uncertainty associated with an exposure point estimate.

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The principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. The quotient method provides an efficient, inexpensive means of identifying high or low risk situations that can allow risk management decisions to be made without the need for further information.

Quotients have also been used to integrate the risks of multiple chemical stressors. In this approach, quotients for the individual constituents in a mixture are generated by dividing each exposure level by a corresponding toxicity endpoint (e.g., an LC_{50}). Although the toxicity of a chemical mixture may be greater (synergism) or less (antagonism) than predicted from the toxicities of individual constituents of the mixture, a quotient addition approach assumes that toxicities are additive or close to additive, which may be true when the modes of action of chemicals in a mixture are similar (e.g., Könemann, 1981; Broderius et al., 1995; Hermens et al., 1984a,b; McCarty and Mackay, 1993; Sawyer and Safe, 1985).

For mixtures of chemicals having dissimilar modes of action, there is some evidence from fish acute toxicity tests with industrial organic chemicals that strict additivity or less-than-strict additivity is common, while antagonistic and synergistic responses are rare (Broderius, 1991). These experiences suggest that caution should be used when predicting that chemicals in a mixture will act independently of one another. However, these relationships observed with aquatic organisms may not be relevant for other endpoints, exposure scenarios, and species. When the mode of action for constituent chemicals are unknown, the assumptions and rationale concerning chemical interactions must be clearly stated.

The application of the quotient method is restricted by a number of limitations (see Smith and Cairns, 1993; Suter, 1993a). While a quotient can be useful in answering whether risks are high or low, it may not be helpful to a risk manager who needs to make a decision requiring a quantification of risks. For example, it is seldom useful to say that a risk mitigation approach will reduce a quotient value from 25 to 12, since this reduction cannot by itself be clearly interpreted in terms of effects on an assessment endpoint.

Another potential difficulty with the quotient method is that the point estimate of effect may not reflect the appropriate intensity of effect or exposure pattern for the assessment. For example, an LC_{50} derived from a 96-hour laboratory test using constant exposure levels may not be appropriate for an assessment of effects on reproduction resulting from short-term, pulsed exposures.

The quotient method cannot evaluate secondary effects. Interactions and effects beyond what is predicted from the simple quotient may be critical to characterizing the full extent of impacts from exposure to the stressors (e.g., bioaccumulation).

Finally, in most cases, the quotient method does not explicitly consider uncertainty (e.g., extrapolation from tested species to the species or community of concern). However, some uncertainties can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate (figures 5–2b and 5–3). If exposure variability is quantified, then the point estimate of effects can be compared with a cumulative exposure distribution as described in text note 5–3. Further discussion of comparisons between point estimates of effects and distributions of exposure may be found in Suter et al., 1983.

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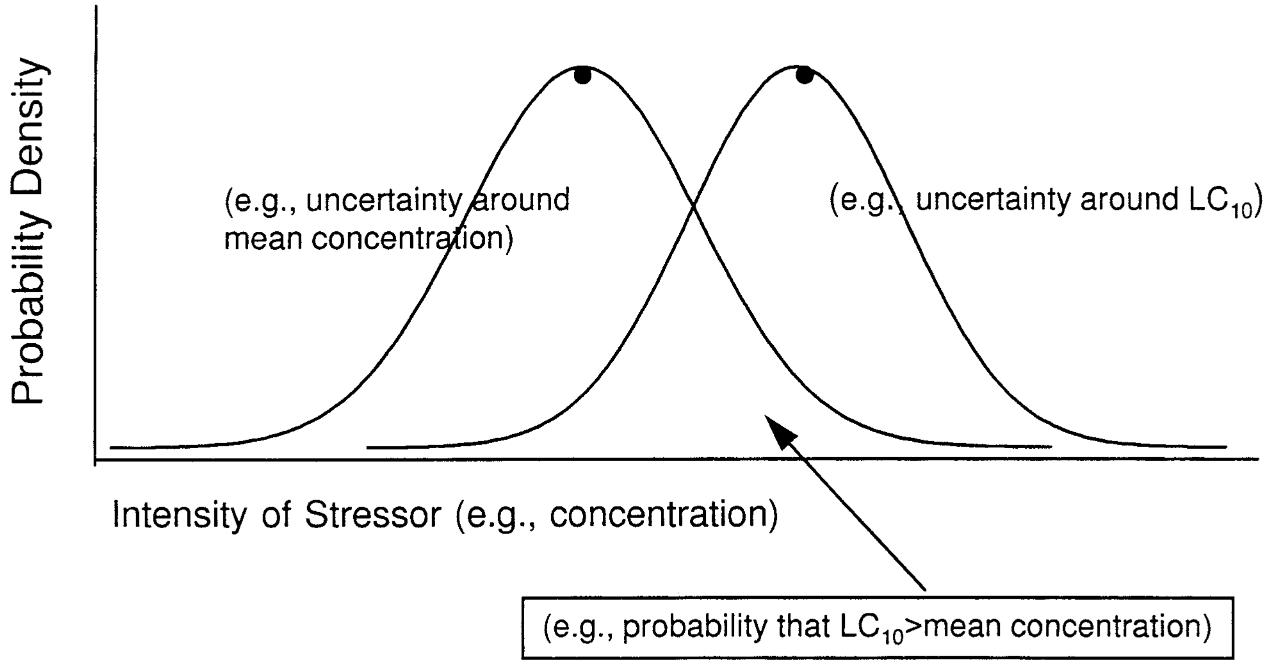

Figure 5-3. Risk estimation techniques: comparison of point estimates with associated uncertainties.

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In view of the advantages and limitations of the quotient method, it is important for risk assessors to consider the points listed below when evaluating quotient method estimates.

- How does the effect concentration relate to the assessment endpoint?
- What extrapolations are involved?
- How does the point estimate of exposure relate to potential spatial and temporal variability in exposure?
- Are data sufficient to provide confidence intervals on the endpoints?

5.1.3. Estimates Incorporating the Entire Stressor-Response Relationship

If the stressor-response profile described a curve relating the stressor level to the magnitude of response, then risk estimation can examine risks associated with many different levels of exposure (figure 5–4). These estimates are particularly useful when the risk assessment outcome is not based on exceedance of a predetermined decision rule such as a toxicity benchmark level.

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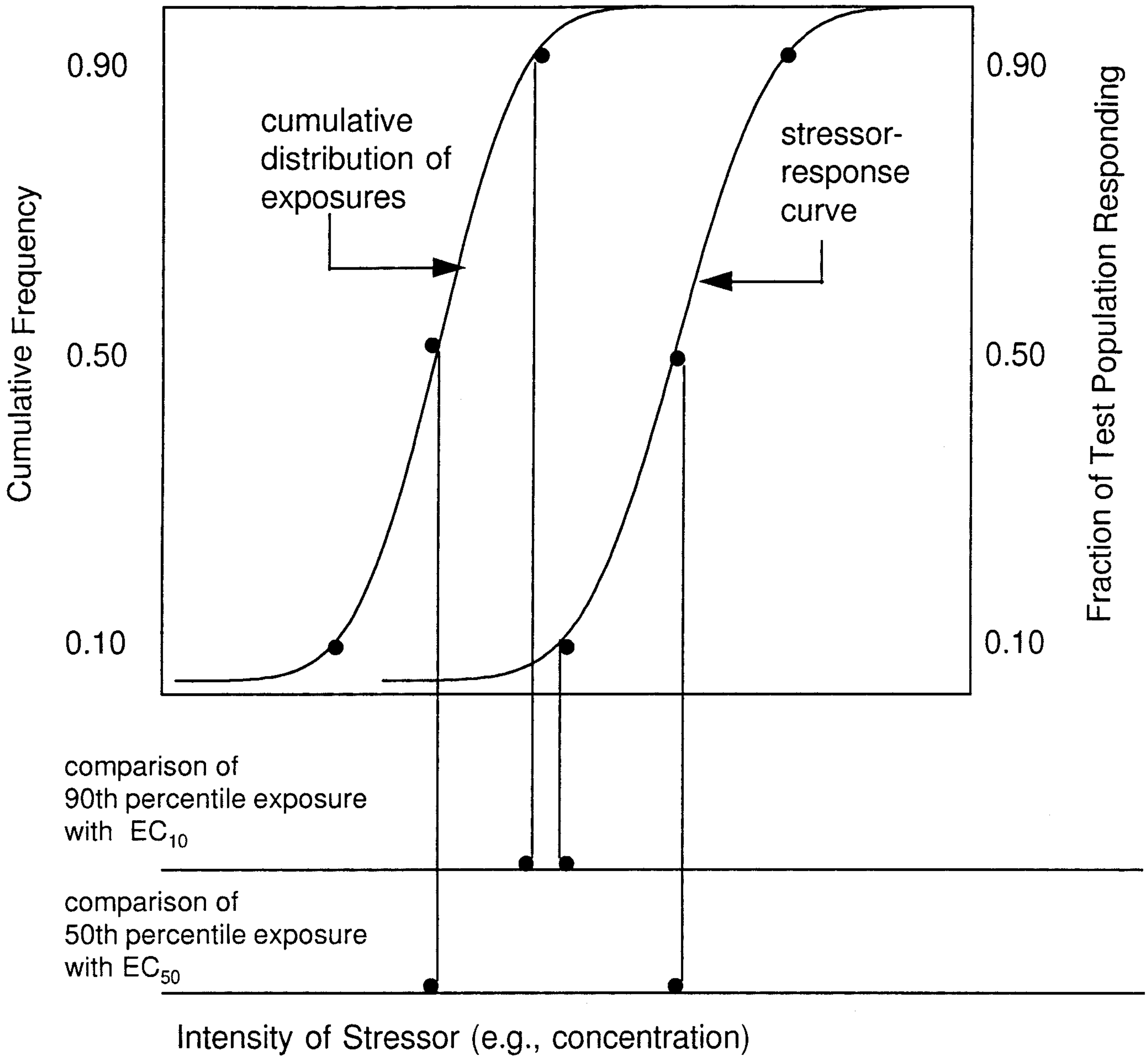

Figure 5-4. Risk estimation techniques: stressor-response curve versus a cumulative distribution of exposures.

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There are both advantages and limitations to comparing a stressor-response curve with an exposure distribution. The steepness of the effects curve shows the magnitude of change in effects associated with incremental changes in exposure, and the capability to predict changes in the magnitude and likelihood of effects for different exposure scenarios can be used to compare different risk management options. Also, uncertainty can be incorporated by calculating uncertainty bounds on the stressor-response or exposure estimates. While comparing exposure and stressor-response curves provides a predictive ability lacking in the quotient method, this approach shares the quotient method's limitations of not evaluating secondary effects, assuming that the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern, and not explicitly considering uncertainties, such as extrapolations from tested species to the species or community of concern.

5.1.4. Estimates Incorporating Variability in Exposure or Effects

If the exposure or stressor-response profiles describe the variability in exposure or effects, then many different risk estimates can be calculated. Variability in exposure can be used to describe risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to describe risks to average or sensitive population members.

A major advantage of this approach is the capability to predict changes in the magnitude and likelihood of effects for different exposure scenarios, thus providing a means for comparing different risk management options. As noted above, comparing distributions also allows one to identify and quantify risks to different segments of the population. Limitations include the increased data requirements compared with previously described techniques and the implicit assumption that the full range of variability in the exposure and effects data is adequately represented. As with the quotient method, secondary effects are not readily evaluated with this technique. Thus, it is desirable to corroborate risks estimated by distributional comparisons with field studies or other lines of evidence. Text note 5–4 and figure 5–5 illustrate the use of cumulative exposure and effects distributions for estimating risk.

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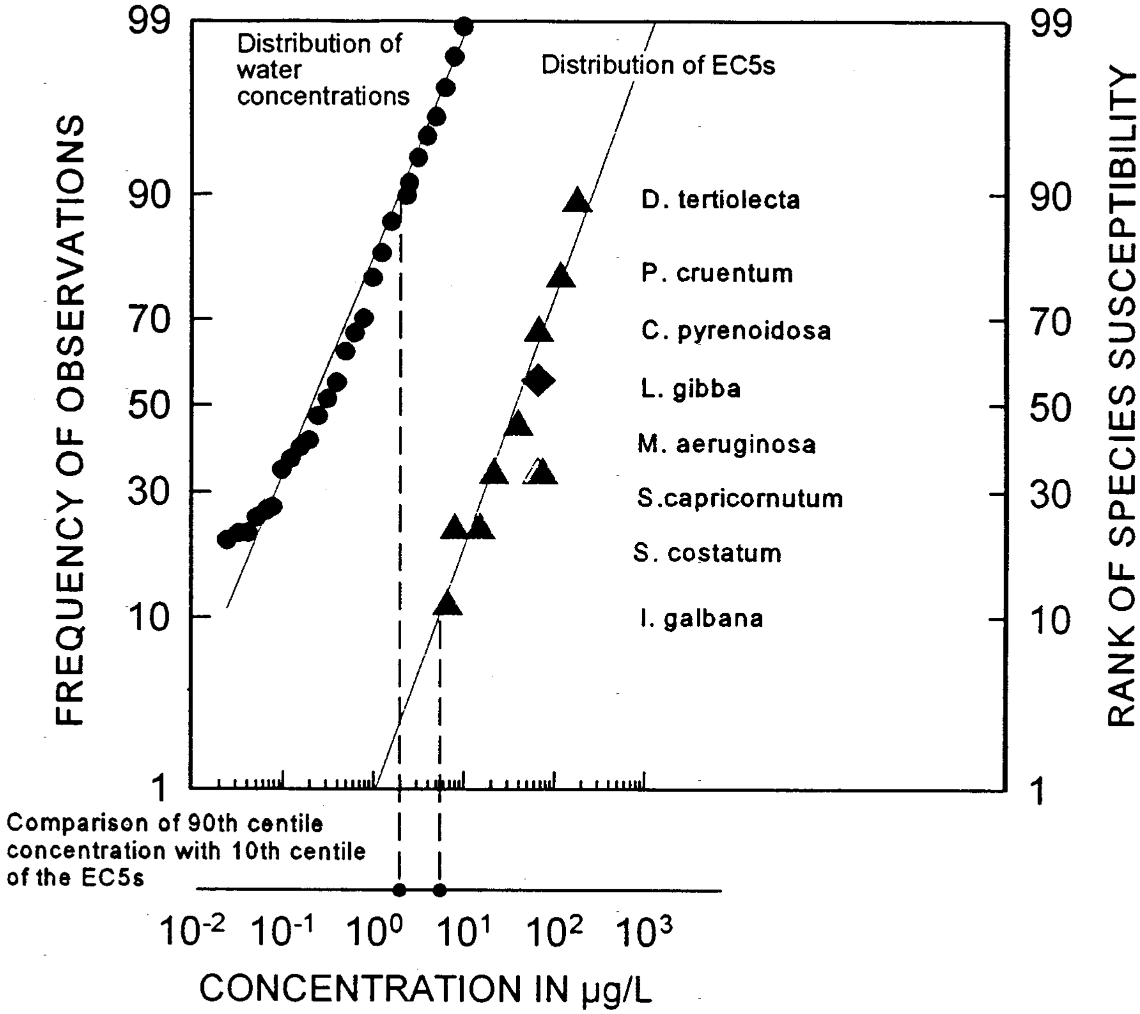

Figure 5-5. Risk estimation techniques: comparison of exposure distribution of an herbicide in surface waters with freshwater single-species toxicity data. See Text note 5-4 for further discussion. Redrawn from SETAC, 1994a.

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5.1.5. Estimates Based on Process Models

Process models are mathematical expressions that represent our understanding of the mechanistic operation of a system under evaluation. They can be useful tools both in the analysis phase (see section 4.1.2.) and the risk characterization phase of ecological risk assessment. For illustrative purposes, we distinguish between process models used for risk estimation that integrate exposure and effects information (text note 5–5) and process models used in the analysis phase that focus on either exposure or effects evaluations.

A major advantage of using process models for risk estimation is the ability to consider ''what if'' scenarios and to forecast beyond the limits of observed data that constrain risk estimation techniques based on empirical data. The process model can also consider secondary effects, unlike other risk estimation techniques such as the quotient method or comparisons of exposure and effect distributions. In addition, some process models may be capable of forecasting the combined effects of multiple stressors (e.g., Barnthouse et al., 1990).

Process model outputs may be point estimates or distributions. In either case, risk assessors should interpret these outputs with care. Process model outputs may imply a higher level of certainty than is appropriate and all too often are viewed without sufficient attention to underlying assumptions. The lack of knowledge on basic life histories for many species and incomplete knowledge on the structure and function of a particular ecosystem is often lost in the model output. Since process models are only as good as the assumptions on which they are based, they should be treated as hypothetical representations of reality until appropriately tested with empirical data. Comparing model results to field data provides a check on whether our understanding of the system was correct (Johnson, 1995) with respect to the risk hypotheses presented in problem formulation.

5.1.6. Field Observational Studies

Field observational studies (surveys) can serve as risk estimation techniques because they provide direct evidence linking exposure to stressors and effects. Field surveys measure biological changes in uncontrolled situations through collection of exposure and effects data at sites identified in problem formulation. A key issue with field surveys is establishing causal relationships between stressors and effects (section 4.3.1.2).

A major advantage of field surveys is that they provide a reality check on other risk estimates, since field surveys are usually more representative of both exposures and effects (including secondary effects) found in natural systems than are estimates generated from laboratory studies or theoretical models (text note 5–6). On the other hand, field data may not constitute reality if they are flawed due to poor experimental design, biased in sampling or analytical techniques, or fail to measure critical components of the system or random variations (Johnson, 1995). A lack of observed effects in a field survey may occur because the measurements are insufficiently sensitive to detect ecological effects, and, unless causal relationships are carefully examined, effects that are observed may be caused by factors unrelated to the stressor(s) of concern. Finally, field surveys taken at one point in time are usually not predictive; they describe effects associated with only one scenario (i.e., the one that exists).

5.2. Risk Description

After risks have been estimated, risk assessors need to integrate and interpret the available information into conclusions about risks to the assessment endpoints. In some cases, risk assessors may have quantified the relationship between assessment endpoints and measures of effect in the analysis stage (section 4.3.1.3). In other situations, qualitative links to assessment endpoints are part of the risk description. For example, if the assessment endpoints are survival of fish, aquatic invertebrates, and algae, risks may be estimated using a quotient method based on LC_{50c}. Regardless of the risk estimation technique, the technical narrative supporting the estimates is as important as the risk estimates themselves.

Risk descriptions include an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the adverse effects on the assessment endpoint.

5.2.1. Lines of Evidence

Confidence in the conclusions of a risk assessment may be increased by using several lines of evidence to interpret and compare risk estimates. These lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints, such as quotient estimates, modeling results, field experiments, or field observations. (Note that the term ''weight of evidence'' is sometimes used in legal discussions or in other documents, e.g., Urban and Cook, 1986; Menzie et al., 1996. We use the phrase lines of evidence to emphasize that both qualitative evaluation and quantitative weightings may be used.)

Some of the factors that the risk assessor should consider when evaluating separate lines of evidence are:

- The relevance of evidence to the assessment endpoints
- The relevance of evidence to the conceptual model
- The sufficiency and quality of data and experimental designs used in key studies
- The strength of cause/effect relationships
- The relative uncertainties of each line of evidence and their direction.

This process involves more than just listing the factors that support or refute the risk. The risk assessor should carefully examine each factor and evaluate its contribution to the risk assessment.

For example, consider the two lines of evidence described for the carbofuran example (text notes 5–2 and 5–6): quotients and field studies. Both approaches are relevant to the assessment endpoint (survival of birds that forage in agricultural areas where carbofuran is applied), and both are relevant to the exposure scenarios described in the conceptual model (figure 3–2). However, the quotients are limited in their ability to express incremental risks (e.g., how much greater risk is expressed by a quotient of ''2'' versus a quotient of ''4''), while the field studies had some design flaws (text note 5–6). Nevertheless, because of the great preponderance of the data, the strong evidence of causal relationships from the field studies, and the consistency between these two lines of evidence, confidence in a conclusion of high risk to the assessment endpoint is supported.

Sometimes lines of evidence do not point toward the same conclusion. When they disagree, it is important to distinguish between true inconsistencies and those related to differences in statistical powers of detection. For example, a model may predict adverse effects that were not observed in a field survey. The risk assessor should ask whether the experimental design of the field study had sufficient power to detect the predicted difference or whether the endpoints measured were comparable with those used in the model.

Conversely, the model may have been unrealistic in its predictions. While it may be possible to use numerical weighting techniques for evaluating various lines of evidence, in most cases qualitative evaluations based on professional judgment are appropriate for sorting through conflicting lines of evidence. While iteration of the risk assessment process and collection of additional data may help resolve uncertainties, this option is not always available.

5.2.2. Determining Ecological Adversity

At this point in risk characterization, the changes expected in the assessment endpoints have been estimated and described. The next step is to interpret whether these changes are considered adverse. Adverse changes are those of concern ecologically or socially (section 1). Determining adversity is not always an easy task and frequently depends on the best professional judgment of the risk assessor.

Five criteria are proposed for evaluating adverse changes in assessment endpoints:

- Nature of effects.
- Intensity of effects.
- Spatial scale.
- Temporal scale.
- Potential for recovery.

The extent to which the five criteria are evaluated depends on the scope and complexity of the ecological risk assessment. However, understanding the underlying assumptions and science policy judgments is important even in simple cases. For example, when exceedance of a previously established decision rule such as a benchmark stressor level is used as evidence of adversity (e.g., see Urban and Cook, 1986, or Nabholz, 1991), the reasons why exceedences of the benchmark are considered adverse should be clearly understood.

To distinguish ecological changes that are adverse from those ecological events that are within the normal pattern of ecosystem variability or result in little or no significant alteration of biota, it is important to consider the nature and intensity of effects. For example, for an assessment endpoint involving survival, growth, and reproduction of a species, do predicted effects involve survival and reproduction or only growth? If survival of offspring will be affected, by what percentage will it diminish?

It is important for risk assessors to consider both the ecological and statistical contexts of an effect when evaluating intensity. For example, a statistically significant 1% decrease in fish growth (text note 5–7) may not be relevant to an assessment endpoint of fish population viability, and a 10% decline in reproduction may be worse for a population of slowly reproducing trees than for rapidly reproducing planktonic algae.

Natural ecosystem variation can make it very difficult to observe (detect) stressor-related perturbations. For example, natural fluctuations in marine fish populations are often large, with intra- and interannual variability in population levels covering several orders of magnitude. Furthermore, cyclic events (e.g., bird migration, tides) are very important in natural systems. Predicting the effects of anthropogenic stressors against this background of variation can be very difficult. Thus, a lack of statistically significant effects in a field study does not automatically mean that adverse ecological effects are absent. Rather, risk assessors must consider factors such as statistical power to detect differences, natural variability, and other lines of evidence in reaching their conclusions.

Spatial and temporal scales need to be considered in assessing the adversity of the effects. The spatial dimension encompasses both the extent and pattern of effect as well as the context of the effect within the landscape. Factors to consider include the absolute area affected, the extent of critical habitats affected compared with a larger area of interest, and the role or use of the affected area within the landscape.

Adverse effects to assessment endpoints vary with the absolute area of the effect. A larger affected area may be (1) subject to a greater number of other stressors, increasing the complications from stressor interactions; (2) more likely to contain sensitive species or habitats; or (3) more susceptible to landscape-level changes because many ecosystems may be altered by the stressors.

Nevertheless, a smaller area of effect is not always associated with lower risk. The function of an area within the landscape may be more important than the absolute area. Destruction of small but unique areas, such as critical wetlands, may have important effects on local wildlife populations. Also, in river systems, both riffle and pool areas provide important microhabitats that maintain the structure and function of the total river ecosystem. Stressors acting on some of these microhabitats may present a significant risk to the entire system.

Spatial factors are important for many species because of the linkages between ecological landscapes and population dynamics. Linkages between one or more landscapes can provide refugia for affected populations, and species may require adequate corridors between habitat patches for successful migration.

The temporal scale for ecosystems can vary from seconds (photosynthesis, prokaryotic reproduction) to centuries (global climate change). Changes within a forest ecosystem can occur gradually over decades or centuries and may be affected by slowly changing external factors such as climate. When interpreting ecological adversity, risk assessors should recognize that the time scale of stressor-induced changes operates within the context of multiple natural time scales. In addition, temporal responses for ecosystems may involve intrinsic time lags, so that responses from a stressor may be delayed. Thus, it is important to distinguish the long-term impacts of a stressor from the immediately visible effects. For example, visible changes resulting from eutrophication of aquatic systems (turbidity, excessive macrophyte growth, population decline) may not become evident for many years after initial increases in nutrient levels.

Considering the temporal scale of adverse effects leads logically to a consideration of recovery. Recovery is the rate and extent of return of a population or community to a condition that existed before the introduction of a stressor. (While this discussion deals with recovery as a result of natural processes, risk mitigation options may include restoration activities to facilitate or speed up the recovery process.) Because ecosystems are dynamic and even under natural conditions are constantly changing in response to changes in the physical environment (weather, natural catastrophes, etc.) or other factors, it is unrealistic to expect that a system will remain static at some level or return to exactly the same state that it was before it was disturbed (Landis et al., 1993). Thus, the attributes of a ''recovered'' system must be carefully defined. Examples might include productivity declines in an eutrophic system, reestablishment of a species at a particular density, species recolonization of a damaged habitat, or the restoration of health of diseased organisms.

Recovery can be evaluated in spite of the difficulty in predicting events in ecological systems (e.g., Niemi et al., 1990). For example, it is possible to distinguish changes that are usually reversible (e.g., recovery of a stream from sewage effluent discharge), frequently irreversible (e.g., establishment of introduced species), and always irreversible (e.g., species extinction). It is important for risk assessors to consider whether significant structural or functional changes have occurred in a system that might render changes irreversible. For example, physical alterations such as deforestation in the coastal hills of Venezuela in recent history and Britain in the Neolithic period changed soil structure and seed sources such that forests cannot easily grow again (Fisher and Woodmansee, 1994).

Risk assessors should note natural disturbance patterns when evaluating the likelihood of recovery from anthropogenic stressors. Ecosystems that have been subjected to repeated natural disturbances may be more vulnerable to anthropogenic stressors (e.g., overfishing, logging of old-growth forest). Alternatively, if an ecosystem has become adapted to a disturbance pattern, it may be affected when the disturbance is removed (fire-maintained grasslands). The lack of natural analogues make it difficult to predict recovery from novel anthropogenic stressors (e.g., synthetic chemicals).

The relative rate of recovery can also be estimated. For example, fish populations in a stream are likely to recover much faster from exposure to a degradable chemical than from habitat alterations resulting from stream channelization. Risk assessors can use knowledge of factors such as the temporal scales of organisms' life histories, the availability of adequate stock for recruitment, and the interspecific and trophic dynamics of the populations in evaluating the relative rates of recovery. A fisheries stock or forest might recover in several decades, a benthic infaunal community in years, and a planktonic community in weeks to months.

Appendix E illustrates how the criteria for ecological adversity (nature and intensity of effects, spatial and temporal scales, and recovery) might be used in evaluating two cleanup options for a marine oil spill. This example also shows that recovery of a system depends not only on how quickly a stressor is removed but also on how any cleanup efforts affect the recovery.

5.3. Reporting Risks

When risk characterization is complete, the risk assessors should be able to estimate ecological risks, indicate the overall degree of confidence in the risk estimates, cite lines of evidence supporting the risk estimates, and interpret the adversity of ecological effects. Usually this information is included in a risk assessment report (sometimes referred to as a risk characterization report because of the integrative nature of risk characterization). This section describes elements that risk assessors should consider when preparing a risk assessment report.

Like the risk assessment itself, a risk assessment report may be brief or extensive depending on the nature of and the resources available for the assessment. While it is important to address the elements described below, risk assessors must judge the appropriate level of detail required. The report need not be overly complex or lengthy, depending on the nature of the risk assessment and the information required to support a risk management decision. In fact, it is important that information be presented clearly and concisely.

While the breadth of ecological risk assessment precludes providing a detailed outline of reporting elements, the risk assessor should consider the elements listed in text note 5–8 when preparing a risk assessment report.

To facilitate mutual understanding, it is critical that the risk assessment results are properly presented. Agency policy requires that risk characterizations be prepared ''in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency'' (U.S. EPA 1995c). Ways to achieve such characteristics are described in text note 5–9.

After the risk assessment report is prepared, the results are discussed with risk managers. Section 6 provides information on communication between risk assessors and risk managers, describes the use of the risk assessment in a risk management context, and briefly discusses communication of risk assessment results from risk managers to the public.

6. Relating Ecological Information to Risk Management Decisions

After characterizing risks and preparing a risk assessment report (section 5), risk assessors discuss the results with risk managers (figure 5–1). Risk managers use risk assessment results along with other factors (e.g., economic or legal concerns) in making environmental decisions. The results also provide a basis for communicating risks to the public.

Mutual understanding between risk assessors and risk managers can be facilitated if the questions listed in text note 6–1 are addressed. Risk managers need to know what the major risks (or potential risks) are with respect to assessment endpoints and have an idea of whether the conclusions are supported by a large body of data or if there are significant data gaps. When there is insufficient information to characterize risk at an appropriate level of detail due to a lack of resources, a lack of a consensus on how to interpret information, or other reasons, the issues, obstacles, and correctable deficiencies should be clearly articulated for the risk manager's consideration.

In making a decision regarding ecological risks, risk managers use risk assessment results along with other information that may include social, economic, political, or legal issues. For example, the risk assessment may be used as part of a risk/benefit analysis, which may require translating resources (identified through the assessment endpoints) into monetary values. One difficulty with this approach is that traditional economic considerations may not adequately address things that are not considered commodities, intergenerational resource values or issues of long-term or irreversible effects (U.S. EPA, 1995b). Risk managers may also consider risk mitigation options or alternative strategies for reducing risks. For example, risk mitigation techniques such as buffer strips or lower field application rates can be used to reduce the exposure (and risk) of a new pesticide. Further, risk managers may consider relative as well as absolute risk, for example, by comparing the risk of a new pesticide to other pesticides currently in use. Finally, risk managers consider public opinion and political demands in their decisions. Taken together, these other factors may render very high risks acceptable or very low risks unacceptable.

Risk characterization provides the basis for communicating ecological risks to the public. This task is usually the responsibility of risk managers. Although the final risk assessment document (including its risk characterization sections) can be made available to the public, the risk communication process is best served by tailoring information to a particular audience. It is important to clearly describe the ecological resources at risk, their value, and the monetary and other costs of protecting (and failing to protect) the resources (U.S. EPA, 1995b).

Managers should clearly describe the sources and causes of risks, the potential adversity of the risks (e.g., nature and intensity, spatial and temporal scale, and recovery potential). The degree of confidence in the risk assessment, the rationale for the risk management decision, and the options for reducing risk are also important (U.S. EPA, 1995b). Other risk communication considerations are provided in text note 6–2.

Along with the discussions of risk and communications with the public, it is important for risk managers to consider whether additional follow-on activities are required. Depending on the importance of the assessment, confidence level in the assessment results, and available resources, it may be advisable to conduct another iteration of the risk assessment (starting with problem formulation or analysis) in order to facilitate a final management decision. Another option is to proceed with the decision and develop a monitoring plan to evaluate the results of the decision (see section 1). For example, if the decision was to mitigate risks through exposure reduction, monitoring could help determine whether the desired reduction in exposure (and effects) was achieved.

7. Text Notes

Text Note 1–1. Related Terminology

The following terms overlap to varying degrees with the broad concept of ecological risk assessment used in these guidelines (see Appendix B for definitions):

- Hazard assessment.
- Comparative risk assessment.
- Cumulative ecological risk assessment.
- Environmental impact statement.

Text Note 1–2. Flexibility of the Framework Diagram

The framework process (figure 1–1) is a general representation of a complex and varied group of assessments, but this diagram should not be viewed as rigid and prescriptive. Rather, as illustrated by the examples below, broad applicability of the framework requires a flexible interpretation of the process.

- In problem formulation, an assessment may begin with a consideration of endpoints, stressors, or ecological effects. Problem formulation is frequently interactive and iterative rather than linear.
- In the analysis phase, it may be difficult to maintain a clear distinction between exposure and effects analyses in all but the simplest systems. Exposure and effects frequently become intertwined, as when an initial exposure leads to a cascade of additional exposures and effects. It is important that a risk assessment is based on an understanding of these complex relationships.
- Analysis and risk characterization are shown as separate phases. However, some models may combine the analysis of exposure and effects data with the integration of these data that occurs in risk characterization.

Text Note 1–3. The Iterative Nature of Ecological Risk Assessment

The ecological risk assessment process is by nature iterative. For example, it may take more than one pass through problem formulation to complete planning for the risk assessment, or information gathered in the analysis phase may suggest further problem formulation activities such as modification of the endpoints selected.

To maximize efficient use of limited resources, ecological risk assessments are frequently designed in sequential tiers that proceed from simple, relatively inexpensive evaluations to more costly and complex assessments. Initial tiers are based on conservative assumptions, such as maximum exposure and ecological sensitivity. When an early tier cannot define risk to support a management decision, a higher assessment tier is used that may require either additional data or applying more refined analysis techniques to available data. Iterations proceed until sufficient information is available to support a sound management decision, within the constraints of available resources.

Because a tiered approach can incorporate standardized decision points and supporting analyses, it can be particularly useful for multiple assessments of similar stressors or situations. However, it is difficult to generalize further concerning tiered risk assessments because they are used to answer so many different questions. Examples of organizations that use, are considering, or have advocated using tiered ecological risk assessments include the Canadian government (proposed, Gaudet, 1994), the European Community (E.C., 1993), industry (Cowan et al., 1995), the Aquatic Dialogue Group (SETAC 1994a), and the U.S. EPA Offices of Pesticide Programs (Urban and Cook, 1986), Pollution Prevention and Toxics (Lynch et al., 1994), and Superfund (document in preparation).

Text Note 2–1. Who Are Risk Managers?

Risk managers are individuals and organizations that take responsibility for, or have the authority to take action or require action, to mitigate an identified risk. The expression ''risk manager'' is often used to represent a decisionmaker in agencies like EPA or state environmental offices who has the authority to protect or manage a resource. However, risk managers often represent a diverse group of interested parties that influence the outcome of resource protection efforts. Particularly as the scope of environmental management expands to communities, the meaning of risk manager significantly expands to include decision officials in Federal, state, and local governments, as well as private-sector leaders in commercial, industrial, and private organizations. Risk managers may also include constituency groups, other interested parties, and the public. In situations where a complex of ecosystem values (e.g., watershed resources) is at risk from multiple stressors, many of these groups may act together as risk management teams. For additional insights on risk management and manager roles, see text notes 2–3 and 2–4.

Text Note 2–2. Who Are Risk Assessors?

Risk assessors are a diverse group of professionals who bring a needed expertise to a risk assessment. When a specific risk assessment process is well defined through regulations and guidance, one trained individual may be able to complete a risk assessment if needed information is available (e.g., premanufacture notice of a chemical). However, as more complex risk assessments become common, it will be rare that one individual can provide the necessary breadth of expertise. Every risk assessment team should include at least one professional who is knowledgeable and experienced in using the risk assessment process. Other team members bring specific expertise relevant to the location, the stressors, the ecosystem, and the scientific issues and other expertise as determined by the type of assessment.

Text Note 2–3. Questions Addressed by Risk Managers and Risk Assessors

Questions Principally for Risk Managers:

What is the nature of the problem and the best scale for the assessment?

What are the management goals and decisions needed, and how will risk assessment help?

What are the ecological values of concern?

What are the policy considerations (law, corporate stewardship, societal concerns, environmental justice)?

What precedents are set by previous risk assessments and decisions?

What is the context of the assessment (e.g., industrial, national park)?

What resources (e.g., personnel, time, money) are available?

What level of uncertainty is acceptable?

Questions Principally for Risk Assessors

What is the scale of the risk assessment?

What are the critical ecological endpoints and ecosystem and receptor characteristics?

How likely is recovery and how long will it take?

What is the nature of the problem: past, present, future?

What is our state of knowledge on the problem?

What data and data analyses are available and appropriate?

What are the potential constraints (e.g., limits on expertise, time, availability of methods and data)?

Text Note 2–4. The Role of Interested Parties

The involvement of all interested and affected parties, which ‘‘stakeholder’’ is commonly used to represent, is important to the development of management goals for some risk assessments. The greater the involvement, the broader the base of consensus about those goals. With strong consensus on management goals, decisions are more likely to be supported by all community groups during implementation of management plans. However, the context of this involvement can vary widely, and the ability to achieve consensus often decreases as the size of the management team increases. Where large diverse groups need to come to consensus, social science professionals and methods for consensus building become increasingly important. Interested parties become risk managers when they influence risk reduction. See additional discussion in text note 2–1 and section 2.2.

Text Note 2–5. Sustainability as a Management Goal

Sustainability is used repeatedly as a management goal in a variety of settings (see U.S. EPA, 1995b). To sustain is to prolong, to hold up under, or endure (Merriam-Webster, 1972). Sustainability and other concepts such as biotic or community integrity are very useful as guiding principles for management goals. However, in each case these principles must be explicitly interpreted to support a risk assessment. To do this, key questions need to be addressed: What does sustainability or integrity mean for the particular ecosystem? What must be protected to meet sustainable goals or system integrity? Which ecological resources and processes are to be sustained and why? How will we know we have achieved it? Answers to these questions serve to clarify the goals for a particular ecosystem. Concepts like sustainability and integrity do not meet the criteria for an assessment endpoint (see section 3.3.2).

Text Note 2–6. Management Goals for Waquoit Bay

Waquoit Bay is a small estuary on Cape Cod showing signs of degradation, including loss of eelgrass, fish, and shellfish and increasing macroalgae mats and fish kills. The management goal for Waquoit Bay was established through public meetings, preexisting goals from local organizations, and state and Federal regulations:

Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated freshwater rivers and ponds to (1) support diverse self-sustaining commercial, recreational, and native fish and shell fish populations, and (2) reverse ongoing degradation of ecological resources in the watershed.

To define this goal, it was interpreted into 10 objectives, two of which are:

- Reestablish a self-sustaining scallop population in the bay that can support a viable sport fishery.
- Reduce or eliminate nuisance macroalgal growth.

From these objectives, specific ecological resources in the bay were identified to provide the basis for the risk assessment, one of which is:

Areal extent and patch size of eelgrass beds.

Eelgrass was selected because scallops are dependent directly on eelgrass beds for survival and eelgrass is highly sensitive to excess macroalgal growth.

Text Note 2–7. Questions to Ask About Scope and Complexity

Is this risk assessment legally mandated, addressing a court-ordered decision, or providing guidance to a community?

Are decisions more likely based on assessments of a small area evaluated in-depth or a large-scale area in less detail?

What are the spatial and temporal boundaries of the problem?

What kinds of information are already available compared to what is needed?

How much time can be taken and how many resources are available?

What practicalities constrain data collection?

Is a tiered approach an option?

Text Note 3–1. Avoiding Potential Shortcomings Through Problem Formulation

The importance of problem formulation has been shown repeatedly in the Agency’s analysis of ecological risk assessment case studies and in interactions with senior EPA managers and regional risk assessors (U.S. EPA, 1993a, 1994a). Consistent shortcomings identified in the case studies include (1) absence of clearly defined goals, (2) endpoints that are ambiguous and difficult to define and measure, and (3) failure to identify important risks. These and other shortcomings can be avoided through rigorous development of the products of problem formulation as described in this section of the guidelines.

Text Note 3–2. Uncertainty in Problem Formulation

In each product of problem formulation there are elements of uncertainty, a consideration of what is known and not known about a problem and its setting. The explicit treatment of uncertainty during problem formulation is particularly important because it will have repercussions throughout the remainder of the assessment. Uncertainty is discussed in section 3.4, Conceptual Models, because uncertainty in problem formulation is articulated in these models.

Text Note 3–3. Assessing Available Information: Questions to Ask Concerning Source, Stressor, and Exposure Characteristics, Ecosystem Characteristics, and Effects

Source and Stressor Characteristics

- What is the source? Is it anthropogenic, natural, point source, or diffuse nonpoint?
- What type of stressor is it: chemical, physical, or biological?
- What is the intensity of the stressor (e.g., the dose or concentration of a chemical, the magnitude or extent of physical disruption, the density or population size of a biological stressor)?
- What is the mode of action? How does the stressor act on organisms or ecosystem functions?

Exposure Characteristics

- With what frequency does a stressor event occur (e.g., is it isolated, episodic, or continuous; is it subject to natural daily, seasonal, or annual periodicity)?
- What is its duration? How long does it persist in the environment (e.g., for chemical, what is its half-life, does it bioaccumulate; for physical, is habitat alteration sufficient to prevent recovery; for biological, will it reproduce and proliferate)?
- What is the timing of exposure? When does it occur in relation to critical organism life cycles or ecosystem events (e.g., reproduction, lake overturn)?
- What is the spatial scale of exposure? Is the extent or influence of the stressor local, regional, global, habitat-specific, or ecosystemwide?

• What is the distribution? How does the stressor move through the environment (e.g., for chemical, fate and transport; for physical, movement of physical structures; for biological, life history dispersal characteristics)?

Ecosystems Potentially at Risk

• What are the geographic boundaries? How do they relate to functional characteristics of the ecosystem?
• What are the key abiotic factors influencing the ecosystem (e.g., climatic factors, geology, hydrology, soil type, water quality)?
• Where and how are functional characteristics driving the ecosystem (e.g., energy source and processing, nutrient cycling)?
• What are the structural characteristics of the ecosystem (e.g., species number and abundance, trophic relationships)?
• What habitat types are present?
• How do these characteristics influence the susceptibility (sensitivity and likelihood of exposure) of the ecosystem to the stressor(s)?
• Are there unique features that are particularly valued (e.g., the last representative of an ecosystem type)?
• What is the landscape context within which the ecosystem occurs?

Ecological Effects

• What are the type and extent of available ecological effects information (e.g., field surveys, laboratory tests, or structure-activity relationships)?
• Given the nature of the stressor (if known), which effects are expected to be elicited by the stressor?
• Under what circumstances will effects occur?

Text Note 3–4. Initiating a Risk Assessment: What's Different When Stressors, Effects, or Values Drive the Process?

The reasons for initiating a risk assessment also influence how the risk assessor proceeds through the process of problem formulation. When the assessment is initiated due to concerns about stressors, risk assessors use what is known about the characteristics of the stressor and its source to focus the assessment. Goals are articulated based on how the stressor is likely to cause risk to possible receptors that may become exposed. This information forms the basis for developing conceptual models and selecting assessment endpoints. When an observed effect is the basis for initiating the assessment, endpoints are normally established first. Often these endpoints involve affected ecological entities and their response. Goals for protecting the assessment endpoints are then established, which support the development of conceptual models. The models aid in the identification of the most likely stressor(s). Value-initiated risk assessments are driven up front by goals for the ecological value of concern. These values might involve ecological entities such as species, communities, ecosystems, or places. Based on these goals, assessment endpoints are selected first to serve as an interpretation of the goals. Once selected, the endpoints provide the basis for identifying an array of stressors that may be influencing them, and describing the diversity of potential effects. This information is then captured in the conceptual model(s).

Text Note 3–5. Salmon and Hydropower: Salmon as the Basis for an Assessment Endpoint

A hydroelectric dam is to be built on a river in the Pacific Northwest where anadromous fish such as salmon spawn. Assessment endpoints must be selected to assess potential ecological risk. Of the anadromous fish, salmon that spawn in the river are an appropriate choice because they meet the criteria for good assessment endpoints. Salmon fry and adults are important food sources for a multitude of aquatic and terrestrial species and are major predators of aquatic invertebrates (ecological relevance). Salmon are sensitive to changes in sedimentation and substrate pebble size, require quality cold water habitats, and have difficulty climbing fish ladders. Hydroelectric dams represent significant and normally fatal habitat alteration and physical obstacles to successful salmon breeding and fry survival (susceptibility). Finally, salmon support a large commercial fishery, some species are endangered, and they have ceremonial importance and are key food sources for Native Americans (basis for management goals). ''Salmon reproduction and population maintenance'' is a good assessment endpoint for this risk assessment, and if salmon populations are protected, other anadromous fish populations are likely to be protected as well. However, one assessment endpoint can rarely provide the basis for a risk assessment of complex ecosystems. These are better represented by a set of assessment endpoints.

Text Note 3–6. Cascading Adverse Effects: Primary (Direct) and Secondary (Indirect)

The interrelationships among entities and processes in ecosystems result in the potential for cascading effects: as one population, species, process, or other entity in the ecosystem is altered, other entities are affected as well. Primary, or direct, effects occur when a stressor acts directly on the assessment endpoint and causes an adverse response. Secondary, or indirect, effects occur when the response of an ecological entity to a stressor becomes a stressor to another entity. Secondary effects are not limited in number. They often are a series of effects among a diversity of organisms and processes that cascade through the ecosystem. For example, application of an herbicide on a wet meadow results in direct toxicity to plants. Death of the wetland plants leads to secondary effects such as loss of feeding habitat for ducks, breeding habitat for red-winged black birds, alteration of wetland hydrology that changes spawning habitat for fish, and so forth.

Text Note 3–7. Sensitivity and Secondary Effects: The Mussel-Fish Connection

Native freshwater mussels are endangered in many streams. Management efforts have focused on maintaining suitable habitat for mussels because habitat loss has been considered the greatest threat to this group. However, larval unionid mussels must attach to the gills of a fish host for one month during development. Each species of mussel must attach to a particular host species of fish. In situations where the fish community has been changed, perhaps due to stressors to which mussels are insensitive, the host fish may no longer be available. Mussel larvae will die before reaching maturity as a result. Regardless of how well managers restore mussel habitat, mussels will be lost from this system unless the fish community is restored. In this case, exposure to the absence of a critical resource is the source of risk.

TEXT NOTE 3–8.—EXAMPLES OF MANAGEMENT GOALS AND ASSESSMENT ENDPOINTS

Case	Regulatory context/management goal	Assessment endpoint
Assessing Risks of New Chemical Under Toxic Substances Control Act (Lynch et al., 1994).	Protect ''the environment'' from ''an unreasonable risk of injury'' (TSCA § 2[b] [1] and [2]); protect the aquatic environment. Goal was to exceed a concentration of concern by no more than 20 days a year.	Survival, growth, and reproduction of fish, aquatic invertebrates, and algae.
Special Review of Granular Carbofuran Based on Adverse Effects on Birds (Houseknecht, 1993).	Prevent * * * ''unreasonable adverse effects on the environment'' (FIFRA §§ 3[c][5] and 3[c][6]); using cost-benefit considerations. Goal was no regularly repeated bird kills.	Individual bird survival.
Modeling Future Losses of Bottomland Forest Wetlands (Brody et al., 1993).	National Environmental Policy Act may apply to environmental impact of new levee construction; also Clean Water Act § 404.	(1) Forest community structure and habitat value to wildlife species. (2) Species composition of wildlife community.
Pest Risk Assessment on Importation of Logs From Chile (USDA, 1993).	This assessment was done to help provide a basis for any necessary regulation of the importation of timber and timber products into the United States.	Survival and growth of tree species in the western United States.
Baird and McGuire Superfund Site (terrestrial component); (Burmaster et al., 1991; Callahan et al., 1991; Menzie et al., 1992).	Protection of the environment (CERCLA/SARA)	(1) Survival of soil invertebrates. (2) Survival and reproduction of song birds.
Waquoit Bay Estuary Watershed Risk Assessment.	Clean Water Act—wetlands protection; water quality criteria—pesticides; endangered species. National Estuarine Research Reserve, Massachusetts, Area of Critical Environmental Concern. Goal was to reestablish and maintain water quality and habitat conditions to support diverse self-sustaining commercial, recreational, and native fish, water-dependent wildlife, and shellfish, and reverse ongoing degradation.	(1) Estuarine eelgrass habitat abundance and distribution. (2) Estuarine fish species diversity and abundance. (3) Freshwater pond benthic invertebrate species diversity and abundance.

Text Note 3–9. Common Problems in Selecting Assessment Endpoints

- Endpoint is a goal (e.g., maintain and restore endemic populations).
- Endpoint is vague (e.g., estuarine integrity instead of eelgrass abundance and distribution).
- Ecological entity is better as a measure (e.g., measure emergence of midges for endpoint on feeding of fish).
- Ecological entity may not be as sensitive to the stressor (e.g., catfish versus salmon for sedimentation).
- Ecological resource is not exposed to the stressor (e.g., using insectivorous birds for avian risk of pesticide application to seeds).
- Ecological resources are irrelevant to the assessment (e.g., lake fish in salmon stream).
- Value of a species or attributes of an ecosystem are not fully considered (e.g., mussel-fish connection, see text note 3–7).
- Attribute is not sufficiently sensitive for detecting important effects (e.g., survival compared with recruitment for endangered species).

Text Note 3–10. What Are Risk Hypotheses and Why Are They Important?

Risk hypotheses are proposed answers to questions risk assessors have about what responses assessment endpoints (and measures) will show when they are exposed to stressors and how exposure will occur. Risk hypotheses clarify and codify relationships that are posited through the consideration of available data, information from scientific literature, and the best professional judgment by risk assessors developing the conceptual models. This explicit process opens the risk assessment to peer review and evaluation to ensure the scientific validity of the work. Risk hypotheses are not equivalent to statistical testing of null and alternative hypotheses. However, predictions generated from risk hypotheses can be tested in a variety of ways, including standard statistical approaches.

Text Note 3–11. Examples of Risk Hypotheses

Hypotheses include known information that sets the problem in perspective and the proposed relationships that need evaluation.

Stressor-initiated: Chemicals with a high K_{ow} tend to bioaccumulate. Premanufacture notice (PMN) chemical A has a K_{ow} of 5.5 and similar molecular structure as known chemical stressor B. Hypotheses: Based on the K_{ow} of chemical A, the mode of action of chemical B, and the food web of the target ecosystem, when the PMN chemical is released at a specified rate, it will bioaccumulate sufficiently in 5 years to cause developmental problems in wildlife and fish.

Effects-initiated: Bird kills were repeatedly observed in golf courses following the application of the pesticide carbofuran, which is highly toxic. Hypotheses: Birds die when they consume recently applied granulated carbofuran; as the level of application increases, the number of dead birds increases. Exposure occurs when dead and dying birds are consumed by other animals. Birds of prey and scavenger species will die from eating contaminated birds.

Ecological value-initiated: Waquoit Bay, Massachusetts, supports recreational boating and commercial and recreational shellfishing and is a significant nursery for fish. Large mats of macroalgae clog the estuary, most of the eelgrass has died, and scallops are gone. Hypotheses: Nutrient loading from septic systems, air pollution, and lawn fertilizers cause eelgrass loss by shading from algal growth, and direct toxicity from nitrogen compounds. Fish and shellfish populations are decreasing because of loss of eelgrass habitat and periodic hypoxia.

Text Note 3–12. What Are the Benefits of Developing Conceptual Models?

- The process of creating a conceptual model is a powerful learning tool.
- Conceptual models can be improved as knowledge increases.

• Conceptual models highlight what we know and don't know and can be used to plan future work.
• Conceptual models can be a powerful communication tool. They provide an explicit expression of our assumptions and understanding of a system for others to evaluate.
• Conceptual models provide a framework for prediction and are the template for generating more risk hypotheses.

Text Note 3–13. Uncertainty in Problem Formulation

Uncertainties in problem formulation are manifested in the quality of conceptual models. To describe uncertainty:
• Be explicit in defining assessment endpoints; include both entity and measurable attributes.
• Reduce or define variability by carefully defining boundaries for the assessment.
• Be open and explicit about the strengths and limitations of pathways and relationships depicted in the conceptual model.
• Identify and describe rationale for key assumptions made because of lack of knowledge, model simplification, approximation, or extrapolation.
• Describe data limitations.

Text Note 3–14. Examples of Assessment Endpoints and Measures (see also section 3.5.1)

Assessment Endpoint: Coho salmon breeding success and fry survival.

Measures of Effects

• Egg and fry response to low dissolved oxygen.
• Adult behavior in response to obstacles.
• Spawning behavior and egg survival in response to sedimentation.

Measures of Ecosystem and Receptor Characteristics

• Water temperature, water velocity, and physical obstructions.
• Abundance and distribution of suitable breeding substrate.
• Abundance and distribution of suitable food sources for fry.
• Feeding, resting, and reproductive cycles.
• Natural population structure (proportion of different size and age classes).
• Laboratory evaluation of reproduction, growth, and mortality.

Measures of Exposure

• Number and height of hydroelectric dams.
• Toxic chemical concentrations in water, sediment, and fish tissue.
• Nutrient and dissolved oxygen levels in ambient waters.

Text Note 3–15. Selecting What To Measure

Direct measurement of assessment endpoint responses is often not possible. Under these circumstances, the selection of a surrogate response measure is necessary. The selection of what, where, and how to measure determines whether the risk assessment is still relevant to management decisions about an assessment endpoint. For example, a risk assessment may be conducted to evaluate the potential risk of a pesticide used on seeds. Birds and mammals may be selected as the entities for assessment endpoints. However, to ensure that the organisms selected are susceptible to the pesticide, only those that eat seeds should be chosen. While insectivorous birds may serve as a good surrogate measure for determining the sensitivity of birds to the pesticide, they do not address issues of exposure. To evaluate susceptibility, the appropriate assessment endpoints in this case would be seed-eating birds and mammals. Problem formulations based on assessment endpoints that are both sensitive and likely to be exposed to the stressor will be relevant to management concerns. If assessment endpoints are not susceptible, their use in assessing risk can lead to poor management decisions.

Text Note 3–16. How Do Water Quality Criteria Relate to Assessment Endpoints?

Water quality criteria (U.S. EPA, 1986a) have been developed for the protection of aquatic life from chemical stressors. This text note shows how the elements of a water quality criterion correspond to management goals, assessment endpoints, and measures.

Regulatory Goal

• Clean Water Act, § 101: Protection of the chemical, physical, and biological integrity of the Nation's waters.

Program Management Objective

• Protect 99% of individuals in 95% of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor.

Assessment Endpoints

• Survival of fish, aquatic invertebrate, and algal species under acute exposure.

• Survival, growth, and reproduction of fish, aquatic invertebrate, and algal species under chronic exposure.

Measures of Effect

• Laboratory LC_{50}s for at least eight species meeting certain requirements.
• Chronic NOAELs for at least three species meeting certain requirements.

Measures of Ecosystem and Receptor Characteristics

• Water hardness (for some metals).
• pH.

The water quality criterion is a benchmark level derived from a distributional analysis of single-species toxicity data. It is assumed that the species tested adequately represent the composition and sensitivities of species in a natural community.

Text Note 3–17. Data Quality Objectives (DQO) Process

The DQO process combines elements of both planning and problem formulation in its seven-step format.
Step 1—State the problem. Review existing information to concisely describe the problem to be studied.
Step 2—Identify the decision. Determine what questions the study will try to resolve and what actions may result.
Step 3—Identify inputs to the decision. Identify information and measures needed to resolve the decision statement.
Step 4—Define study boundaries. Specify time and spatial parameters and where and when data should be collected.
Step 5—Develop decision rule. Define statistical parameter, action level, and logical basis for choosing alternatives.
Step 6—Specify tolerable limits on decision errors. Define limits based on the consequences of an incorrect decision.
Step 7—Optimize the design. Generate alternative data collection designs and choose most resource-effective design that meets all DQOs.

Text Note 4–1. Data Collection and the Analysis Phase

Data needs are identified during problem formulation (the analysis plan step), and data are collected before the start of the analysis phase. These data may be collected for the specific purpose of a particular risk assessment, or they may be available from previous studies. If additional data needs are identified as the assessment proceeds, the analysis phase may be temporarily halted while they are collected or the assessor may choose to iterate the problem formulation again. Data collection methods are not described in these guidelines. However, the evaluation of data for the purposes of risk assessment is discussed in section 4.2.

Text Note 4–2. The American National Standard for Quality Assurance

The Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ASQC, 1994) recognizes several areas that are important to ensuring that environmental data will meet study objectives, including:

- Planning and scoping.
- Design of data collection operations.
- Implementation and monitoring of planned operations.
- Assessment and verification of data usability.

Text Note 4–3. Questions for Evaluating a Study's Utility for Risk Assessment

How do study objectives compare with those of the risk assessment?
Are the variables and conditions the study represents compared to those important to the risk assessment?
Was the study design adequate to meet its objectives?
Was the study conducted properly?
How were variability and uncertainty treated and reported?

Text Note 4–4. Considering the Degree of Aggregation in Models

Wiegert and Bartell (1994) suggest the following considerations for evaluating the proper degree of aggregation or disaggregation:

(1) Do not aggregate components with greatly disparate rates of fluxes;
(2) Do not greatly increase the disaggregation of the structural aspects of the model without a corresponding increase in the sophistication of the functional relationships and controls; and
(3) Disaggregate models only insofar as required by the goals of the model to facilitate testing.

Text Note 4–5. Questions for Source Description

Where does the stressor originate?
What environmental medium first receives stressors?
Does the source generate other constituents that will influence a stressor's eventual distribution in the environment?
Are there other sources of the same stressor?
Are there background sources?
Is the source still active?
Does the source produce a distinctive signature that can be seen in the environment, organisms or communities?

Additional Questions for Introduction of Biological Stressors

Is there an opportunity for repeated introduction or escape into the new environment?
Will the organism be present on a transportable item?
Are there mitigation requirements or conditions that would kill or impair the organism before entry, during transport, or at the port of entry?

Text Note 4–6. Questions To Ask in Evaluating Stressor Distribution

What are the important transport pathways?
What characteristics of the stressor influence transport?
What characteristics of the ecosystem will influence transport?
What secondary stressors will be formed?
Where will they be transported?

Text Note 4–7. General Mechanisms of Transport and Dispersal

Physical, Chemical and Biological Stressors

- By air current.
- In surface water (rivers, lakes, streams).
- Over and/or through the soil surface.
- Through ground water.

Primarily Chemical Stressors

- Through the food web.

Primarily Biological Stressors

- Splashing or raindrops.
- Human activity (boats, campers).
- Passive transmittal by other organisms.
- Biological vectors.

Text Note 4–8. Questions To Ask in Describing Contact or Co-Occurrence

Must the receptor actually contact the stressor for adverse effects to occur?
Must the stressor be taken up into a receptor for adverse effects to occur?
What characteristics of the receptors will influence the extent of contact or co-occurrence?
Will abiotic characteristics of the environment influence the extent of contact or co-occurrence?
Will ecosystem processes or community-level interactions influence the extent of contact or co-occurrence?

Text Note 4–9. Example of an Exposure Equation: Calculating a Potential Dose via Ingestion

$$ADD_{pot} = \sum_{k=1}^{m} \left(C_k \times FR_k \times NIR_k\right)$$

Where:

ADD_{pot}=Potential average daily dose (e.g., in mg/kg-day)
C_k=Average contaminant concentration in the k^{th} type of food (e.g., in mg/kg wet weight)
FR_k=Fraction of intake of the k^{th} food type that is from the contaminated area (unitless)
NIR_k=Normalized ingestion rate of the k^{th} food type on a wet-weight basis (e.g., in g food/g body-weight-day).
m=Number of contaminated food types

Source: U.S. EPA, 1993c

Text Note 4–10. Measuring Internal Dose Using Biomarkers and Tissue Residues

Biomarkers, tissue residues, or other bioassessment methods may be useful in estimating or confirming exposure in cases where bioavailability is expected to be a significant issue, but the factors influencing it are not known. They can also be very useful when the metabolism and accumulation kinetics are important factors (McCarty and Mackay, 1993). These methods are most useful when they can be quantitatively linked to the amount of stressor originally contacted by the organism. In addition, they are most useful when the stressor-response relationship expresses the amount of stressor in terms of the tissue residues or biomarkers. Additional information and some considerations for their development can be found in Huggett et al. (1992).

Text Note 4–11. Questions Addressed by the Exposure Profile

How does exposure occur?
What is exposed?
How much exposure occurs? When and where does it occur?
How does exposure vary?
How uncertain are the exposure estimates?
What is the likelihood that exposure will occur?

Text Note 4–12. Questions for Stressor-Response Analysis

Does the assessment require point estimates or stressor-response curves?
Does the assessment require the establishment of a ''no-effect'' level?
Would cumulative effects distributions be useful?

Text Note 4–13. Qualitative Stressor-Response Relationships

The relationship between stressor and response can be described qualitatively, for instance, using categories of high, medium, and low, to describe the intensity of response given exposure to a stressor. For example, Pearlstine et al. (1985) assumed that seeds would not germinate if they were inundated with water at the critical time. This stressor-response relationship was described simply as a yes or no. In most cases, however, the objective is to describe quantitatively the intensity of response associated with exposure, and in the best case, to describe how intensity of response changes with incremental increases in exposure.

Text Note 4–14. Median Effect Levels

Median effects are those effects elicited in 50% of the test organisms exposed to a stressor, typically chemical stressors. Median effect concentrations can be expressed in terms of lethality or mortality and are known as LC_{50} or LD_{50}, depending on whether concentrations (in the diet or in water) or doses (mg/kg) were used. Median effects other than lethality (e.g., effects on growth) are expressed as EC_{50} or ED_{50}. The median effect level is always associated with a time parameter (e.g., 24 or 48 hr). Because these tests seldom exceed 96 hr, their main value lies in evaluating short-term effects of chemicals. Stephan (1977) discusses several statistical methods to estimate the median effect level.

Text Note 4–15. No-Effect Levels Derived From Statistical Hypothesis Testing

Statistical hypothesis tests have typically been used with chronic toxicity tests of chemical stressors that evaluate multiple endpoints. For each endpoint, the objective is to determine the highest test concentration for which effects are not statistically different from the controls (the no observed adverse effect concentration, NOAEC) and the lowest concentration at which effects were statistically significant from the control (the lowest observed adverse effect concentration, LOAEC). The range between the NOAEC and the LOAEC is sometimes called the maximum acceptable toxicant concentration, or MATC. The MATC, which can also be reported as the geometric mean of the NOAEC and the LOAEC, provides a useful reference with which to compare toxicities of various chemical stressors.

Reporting the results of chronic tests in terms of the MATC or GMATC has been widely used within the Agency for evaluating pesticides and industrial chemicals (e.g., Urban and Cook, 1986; Nabholz, 1991).

Text Note 4–16. General Criteria for Causality (Adapted From Fox, 1991)

Criteria strongly affirming causality:

- Strength of association.
- Predictive performance.
- Demonstration of a stressor-response relationship.
- Consistency of association.

Criteria providing a basis for rejecting causality:

- Inconsistency in association.
- Temporal incompatibility.
- Factual implausibility.

Other relevant criteria:

- Specificity of association.
- Theoretical and biological plausibility.

Text Note 4–17. Koch's Postulates (Pelczar and Reid, 1972)

- A pathogen must be consistently found in association with a given disease.
- The pathogen must be isolated from the host and grown in pure culture.
- When inoculated into test animals, the same disease symptoms must be expressed.
- The pathogen must again be isolated from the test organism.

Text Note 4–18. Examples of Extrapolations to Link Measures of Effect to Assessment Endpoints

Every risk assessment has data gaps that must be addressed, but it is not always possible to obtain more information. When there is a lack of time, monetary resources, or a practical means to acquire more data, extrapolations such as those listed below may be the only way to bridge gaps in available data. Extrapolations may be:

- Between taxa (e.g., bluegill to rainbow trout).
- Between responses (e.g., mortality to growth or reproduction).
- From laboratory to field.
- Between geographic areas.
- Between spatial scales.
- From data collected over a short timeframe to longer-term effects.

Text Note 4–19. Questions Related to Selecting Extrapolation Approaches

How specific is the assessment endpoint?

Does the spatial or temporal extent of exposure suggest the need for additional receptors or extrapolation models?

Are the quantity and quality of the data available sufficient for planned extrapolations and models?

Is the proposed extrapolation technique consistent with ecological information?

How much uncertainty is acceptable?

Text Note 4–20. Questions To Consider When Extrapolating From Effects Observed in the Laboratory to Field Effects of Chemicals

Exposure factors:

How will environmental fate and transformation of the chemical effect exposure in the field?

How comparable are exposure conditions and the timing of exposure?

How comparable are the routes of exposure?

How do abiotic factors influence bioavailability and exposure?

How likely are preference or avoidance behaviors?

Effects factors:

What is known about the biotic and abiotic factors controlling populations of the organisms of concern?

To what degree are critical life stage data available?

How may exposure to the same or other stressors in the field have altered organism sensitivity?

Text Note 4–21. Questions Addressed by the Stressor-Response Profile

What ecological entities are affected?

What is the nature of the effect(s)?

What is the intensity of the effect(s)?

Where appropriate, what is the time scale for recovery?

What causal information links the stressor with any observed effects?

How do changes in measures of effects relate to changes in assessment endpoints?

What is the uncertainty associated with the analysis?

Text Note 5–1. Using Qualitative Categories to Estimate Risks of an Introduced Species

The importation of logs from Chile required an assessment of the risks posed by the potential introduction of the bark beetle, Hylurgus ligniperda (USDA, 1993). Experts to judged the potential for colonization and spread of the species, and their opinions were expressed as high, medium, or low as to the likelihood of establishment (exposure) or consequential effects of the beetle. Uncertainties were similarly expressed. A ranking scheme was then used to sum the individual elements into an overall estimate of risk (high, medium, or low). Narrative explanations of risk accompanied the overall rankings.

Text Note 5–2. Applying the Quotient Method

When applying the quotient method to chemical stressors, the effects concentration or dose (e.g., an LC_{50}, LD_{50}, EC_{50}, ED_{50}, NOAEL, or LOAEL) is frequently adjusted by uncertainty modifying factors prior to division into the exposure number (U.S. EPA, 1984; Nabholz, 1991; Urban and Cook, 1986; see section 4.3.1.3), although EPA used a slightly different approach in estimating the risks to the survival of birds that forage in agricultural areas where the pesticide granular carbofuran is applied (Houseknecht, 1993). In this case, EPA calculated the quotient by dividing the estimated exposure levels of carbofuran granules in surface soils (number/ft^2) by the granules/LD_{50} derived from single-dose avian toxicity tests. The calculation yields values with units of LD_{50}/ft^2. It was assumed that a higher quotient value corresponded to an increased likelihood that a bird would be exposed to lethal levels of granular carbofuran at the soil surface. Minimum and maximum values for LD_{50}/ft^2 were estimated for songbirds, upland game birds, and waterfowl that may forage within or near 10 different agricultural crops.

Text Note 5–3. Comparing an Exposure Distribution With a Point Estimate of Effects

The EPA Office of Pollution Prevention and Toxics uses a Probabilistic Dilution Model (PDM3) to generate a distribution of daily average chemical concentrations based on estimated variations in stream flow in a model system. The PDM3 model compares this exposure distribution with an aquatic toxicity test endpoint to estimate how many days in a 1-year period the endpoint concentration is exceeded (Nabholz et al., 1993; U.S. EPA, 1988b). The frequency of exceedance is based on the duration of the toxicity test used to derive the effects endpoint. Thus, if the endpoint was an acute toxicity level of concern, an exceedance would be identified if the level of concern was exceeded for 4 days or more (not necessarily consecutive). The exposure estimates are conservative in that they assume instantaneous mixing of the chemical in the water column and no losses due to physical, chemical, or biodegradation effects.

Text Note 5–4. Comparing Cumulative Exposure and Effects Distributions for Chemical Stressors

Exposure distributions for chemical stressors can be compared with effects distributions derived from point estimates of acute or chronic toxicity values derived from different species (e.g., HCN, 1993; Cardwell et al., 1993; SETAC, 1994a; Solomon et al., 1996). Figure 5–5 shows a distribution of exposure concentrations of an herbicide compared with single-species algal toxicity data for the same chemical. The degree of overlap of the curves indicates the likelihood that a certain percentage of species may be adversely affected. For example, figure 5–5 indicates that the 10th percentile of algal species' EC_5 values is exceeded less than 10% of the time.

The predictive value of this approach is evident. The degree of risk reduction that could be achieved by changes in exposure associated with proposed risk mitigation options can be readily determined by comparing modified exposure distributions with the effects distribution curve.

When using effects distributions derived from single-species toxicity data, risk assessors should consider the following questions:

- Does the subset of species for which toxicity test data are available represent the range of species present in the environment?
- Are particularly sensitive (or insensitive) groups of organisms represented in the distribution?
- If a criterion level is selected—e.g., protect 95% of species—does the 5% of potentially affected species include organisms of ecological, commercial, or recreational significance?

Text Note 5–5. Estimating Risk With Process Models

Models that integrate both exposure and effects information can be used to estimate risk. During risk estimation, it is important that both the strengths and limitations of a process model approach be highlighted. Brody et al. (1993; see Appendix D) linked two process models to integrate exposure and effects information and forecast spatial and temporal changes in forest communities and their wildlife habitat value. While the models were useful for projecting long-term effects based on an understanding of the underlying mechanisms of change in forest communities and wildlife habitat, they could not evaluate all possible stressors of concern and were limited in the plant and wildlife species they could consider. Understanding both the strengths and limitations of models is essential for accurately representing the overall confidence in the assessment.

Text Note 5–6. An Example of Field Methods Used for Risk Estimation

Along with quotients comparing field measures of exposure with laboratory acute toxicity data (text note 5–2), EPA evaluated the risks of granular carbofuran to birds based on incidents of bird kills following carbofuran applications. Over 40 incidents involving nearly 30 species of birds were documented. Although reviewers identified problems with individual field studies (e.g., lack of appropriate control sites, lack of data on carcass-search efficiencies, no examination of potential synergistic effects of other pesticides, and lack of consideration of other potential receptors such as small mammals), there was so much evidence of mortality associated with carbofuran application that the study deficiencies did not alter the conclusions of high risk found by the assessment (Houseknecht, 1993).

Text Note 5–7. What Are Statistically Significant Effects?

Statistical testing is the "statistical procedure or decision rule which leads to establishing the truth or falsity of a hypothesis. * * *" (Alder and Roessler, 1972). Statistical significance is based on the number of data points, the nature of their distribution, whether inter-treatment variance exceeds intra-treatment variance in the data, and the a priori significance level (α). The types of statistical tests and the appropriate protocols (e.g., power of test) for these tests should be established as part of the analysis plan during problem formulation.

Text Note 5–8. Possible Risk Assessment Report Elements

- Describe risk assessor/risk manager planning results.
- Review the conceptual model and the assessment endpoints.
- Discuss the major data sources and analytical procedures used.
- Review the stressor-response and exposure profiles.
- Describe risks to the assessment endpoints, including risk estimates and adversity evaluations.
- Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them.

fl Discuss the degree of scientific consensus in key areas of uncertainty.

fl Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results.

fl Discuss science policy judgments or default assumptions used to bridge information gaps, and the basis for these assumptions.

Text Note 5–9. Clear, Transparent, Reasonable, and Consistent Risk Characterizations

For clarity:

- Be brief; avoid jargon.
- Make language and organization understandable to risk managers and the informed lay person.
- Fully discuss and explain unusual issues specific to a particular risk assessment.

For transparency:

- Identify the scientific conclusions separately from policy judgments.
- Clearly articulate major differing viewpoints of scientific judgments.
- Define and explain the risk assessment purpose (e.g., regulatory purpose, policy analysis, priority setting).
- Fully explain assumptions and biases (scientific and policy).

For reasonableness:

- Integrate all components into an overall conclusion of risk that is complete, informative, and useful in decision making.
- Acknowledge uncertainties and assumptions in a forthright manner.
- Describe key data as experimental, state of the art, or generally accepted scientific knowledge.
- Identify reasonable alternatives and conclusions that can be derived from the data.
- Define the level of effort (e.g., quick screen, extensive characterization) along with the reason(s) for selecting this level of effort.
- Explain the status of peer review.

For consistency with other risk characterizations:

- Describe how the risks posed by one set of stressor(s) compare with the risks posed by a similar stressor(s) or similar environmental conditions.
- Indicate how the strengths and limitations of the assessment compare with past assessments.

Text Note 6–1. Questions Regarding Risk Assessment Results (Adapted From U.S. EPA, 1993d)

Questions principally for risk assessors to ask:

- Are the risks sufficiently well defined (and data gaps small enough) to support a risk management decision?
- Was the right problem analyzed?
- Was the problem adequately characterized?

Questions principally for risk managers to ask:

- What effects might occur?
- How adverse are the effects?
- How likely is it that effects will occur?
- When and where do the effects occur?
- How confident are you in the conclusions of the risk assessment?
- What are the critical data gaps, and will information be available in the near future to fill these gaps?
- Are more ecological risk assessment iterations required?
- How could monitoring help evaluate results of the risk management decision?

Text Note 6–2. Risk Communication Considerations for Risk Managers (U.S. EPA, 1995c)

- Plan carefully and evaluate the success of your communication efforts.
- Coordinate and collaborate with other credible sources.
- Accept and involve the public as a legitimate partner.
- Listen to the public's specific concerns.
- Be honest, frank, and open.
- Speak clearly and with compassion.
- Meet the needs of the media.

Text Note A–1. Stressor vs. Agent

Agent has been suggested as an alternative for the term stressor (Suter et al., 1994). Agent is thought to be a more neutral term than stressor, but agent is also associated with certain classes of chemicals (e.g., chemical warfare agents). In addition, agent has the connotation of the entity that is initially released from the source, whereas stressor has the connotation of the entity that causes the response. Agent is used in EPA's Guidelines for Exposure Assessment (U.S. EPA, 1992d) (i.e., with exposure defined as ''contact of a chemical, physical, or biological agent''). These two terms are considered to be nearly synonymous, but stressor is used throughout these guidelines for internal consistency.

Appendix A—Changes From EPA'S Ecological Risk Assessment Framework

EPA has gained much experience with the ecological risk assessment process since the publication of the Framework Report (U.S. EPA, 1992a) and has received many suggestions for modifications of both the process and the terminology. While EPA is not recommending major changes in the overall ecological risk assessment process, proposed modifications are summarized here to assist those who may already be familiar with the Framework Report. Changes in the diagram are discussed first, followed by changes in terminology and definitions.

A.1. Changes in the Framework Diagram

The revised framework diagram is shown in figure 1–2. Within each phase, rectangular boxes are used to designate inputs, hexagon-shaped boxes indicate actions, and circular boxes represent outputs. There have been only minor changes in the wording for the boxes outside of the risk assessment process (planning and communications between risk assessors and risk managers; acquire data, iterate process, monitor results). ''Iterate process'' was added to emphasize the iterative (and frequently tiered) nature of risk assessment.

The new diagram of problem formulation contains several changes. The hexagon encloses information about stressors, sources, and exposures, ecological effects, and the ecosystem at risk to better reflect the importance of integrating this information before selecting assessment endpoints and building conceptual models. The three products of problem formulation are enclosed in circles. Assessment endpoints are shown as a key product that drives conceptual model development. The conceptual model remains a central product of problem formulation. The analysis plan has been added as an explicit product of problem formulation to emphasize the need to plan data evaluation and interpretation before analyses begin. It is in the analysis plan that measures of ecological effects (measurement endpoints) are identified.

In the analysis phase, the left-hand side of figure 1–2 shows the general process of characterization of exposure, and the right-hand side shows the characterization of ecological effects. These two aspects of analysis must closely interact to produce compatible output that can be integrated in risk characterization. The dotted line and hexagon that includes both the exposure and ecological response analyses emphasize this interaction. In addition, the first three boxes in analysis now include the measures of exposure, effects, and ecosystem and receptor characteristics that provide input to the exposure and ecological response analyses.

Experience with the application of risk characterization as outlined in the Framework Report suggests the need for several modifications in this process. Risk estimation entails the integration of exposure and effects estimates along with an analysis of uncertainties. The process of risk estimation outlined in the Framework Report separates integration and uncertainty. The original purpose for this separation was to emphasize the importance of estimating uncertainty. This separation is no longer needed since uncertainty analysis is now explicitly addressed in most risk integration methods.

The description of risk is similar to the process described in the Framework Report. Topics included in the risk description include the lines of evidence that support causality and a determination of the ecological adversity of observed or predicted effects. Considerations for reporting risk assessment results are also described.

A.2. Changes in Definitions and Terminology

Except as noted below, these guidelines retain definitions used in the Framework Report (see Appendix B). Some definitions have been revised, especially those related to endpoints and exposure. Some changes in the classification of uncertainty from the Framework Report are also described in this section. It is likely that these terms will continue to generate considerable discussion among risk assessors.

A.2.1. Endpoint Terminology

The Framework Report uses the assessment and measurement endpoint terminology of Suter (1990) but offers no specific terms for measurements of stressor levels or ecosystem attributes. Experience has shown that stressor measurements are sometimes inappropriately called measurement endpoints; measurement endpoints should be ''* * * measurable responses to a stressor that are related to the valued characteristics chosen as assessment endpoints'' (U.S. EPA, 1992a; Suter, 1990; emphasis added). These guidelines replace measurement endpoint with measure of effect, which is defined as a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint (Suter, 1990; U.S. EPA, 1992a). (An assessment endpoint is ''an explicit expression of the environmental value to be protected'' [U.S. EPA, 1992a].) Since data other than those required to evaluate responses (i.e., measures of effects) are required for an ecological risk assessment, two additional types of measures are used. Measures of exposure include stressor and source measurements, while measures of ecosystem and receptor characteristics include, for example, habitat measures, soil parameters, water quality conditions, or life history parameters that may be necessary to better characterize exposure or effects. Any of the three types of measures may be actual data (e.g., mortality), summary statistics (e.g., an LC_{50}), or estimated values (e.g., an LC_{50} estimated from a structure-activity relationship).

A.2.2. Exposure Terminology

These guidelines define exposure in a manner that is relevant to any chemical, physical, or biological entity. While the broad concepts are the same, the language and approaches vary depending on whether a chemical, physical, or biological entity is the subject of assessment. Key exposure-related terms and their definitions are:

- Source. A source is an entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors. Sources may include a waste treatment plant, a pesticide application, a logging operation, introduction of exotic organisms, or a dredging project.
- Stressor. A stressor is any physical, chemical, or biological entity that can induce an adverse response. This term is used broadly to encompass entities that cause primary effects and those primary effects that can cause secondary (i.e., indirect) effects. Stressors may be chemical (e.g., toxics or nutrients), physical (e.g., dams, fishing nets, or suspended sediments), or biological (e.g., exotic or genetically engineered organisms). While risk assessment is concerned with the characterization of adverse responses, under some circumstances a stressor may be neutral or produce effects that are beneficial to certain ecological components (see text note A–1). Primary effects may also become stressors. For example, a change in a bottomland hardwood plant community affected by rising water levels can be thought of as a stressor influencing the wildlife community. Stressors may also be formed through abiotic interactions; for example, the increase in ultraviolet light reaching the earth's surface results from the interaction of the original stressors released (chlorofluorocarbons) with the ecosystem (stratospheric ozone).
- Exposure. As discussed above, these guidelines use the term exposure broadly after the common definition of expose: ''to submit or subject to an action or influence'' (Merriam-Webster, 1972). Used in this way, exposure applies to physical and biological stressors as well as to chemicals (organisms are commonly said to be exposed to radiation, pathogens, or heat). Exposure is also applicable to higher levels of biological organization, such as exposure of a benthic community to dredging, exposure of an owl population to habitat modification, or exposure of a wildlife population to hunting. Although the operational definition of exposure, particularly the units of measure, depends on the stressor and receptor (defined below), the following general definition is applicable: Exposure is the contact or co-occurrence of a stressor with a receptor.
- Receptor. The receptor is the ecological component exposed to the stressor. This term may refer to tissues, organisms, populations, communities, and ecosystems. While either ''ecological component'' (U.S. EPA, 1992a) or ''biological system'' (Cohrssen and Covello, 1989) are alternative terms, ''receptor'' is usually clearer in discussions of exposure where the emphasis is on the stressor-receptor relationship. As discussed below, both disturbance and stress regime have been suggested as alternative terms for exposure. Neither term is used in these guidelines, which instead use exposure as broadly defined above.
- Disturbance. A disturbance is any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment (modified slightly from White and Pickett, 1985). Defined in this way, disturbance is clearly a kind of exposure (i.e., an event that subjects a receptor, the disturbed system, to the actions of a stressor). Disturbance may be a useful alternative to stressor specifically for physical stressors that are deletions or modifications (e.g., logging, dredging, flooding).
- Stress Regime. The term stress regime has been used in at least three distinct ways: (1) To characterize exposure to multiple chemicals or to both chemical and nonchemical stressors (more clearly described as multiple exposure, complex exposure, or exposure to mixtures), (2) as a synonym for exposure that is intended to avoid overemphasis on chemical exposures, and (3) to describe the series of interactions of exposures and effects resulting in secondary exposures, secondary effects, and, finally, ultimate effects (also known as risk cascade [Lipton et al., 1993]) or causal chain, pathway, or network (Andrewartha and Birch, 1984). Because of the potential for confusion and the availability of other clearer terms, this term is not used in these guidelines.

A.2.3. Uncertainty Terminology

The Framework Report divided uncertainty into conceptual model formation, information and data, stochasticity, and error. These guidelines discuss uncertainty throughout the process, focusing on the conceptual model (section 3.4.3), the analysis phase (section 4.1.3), and the incorporation of uncertainty in risk estimates (section 5.1). The bulk of the discussion appears in section 4.1.3, where the discussion is organized according to the following sources of uncertainty:

- Unclear communication.
- Descriptive errors.
- Variability.
- Data gaps.
- Uncertainty about a quantity's true value.

• Model structure uncertainty (process models).

• Uncertainty about a model's form (empirical models).

Appendix B.—Key Terms (Adapted From U.S. EPA, 1992a)

Agent—Any physical, chemical, or biological entity that can induce an adverse response (synonymous with stressor).

Assessment endpoint—An explicit expression of the environmental value that is to be protected. An assessment endpoint includes both an ecological entity and specific attributes of that entity. For example, salmon are a valued ecological entity; reproduction and population maintenance of salmon form an assessment endpoint.

Characterization of ecological effects—A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

Characterization of exposure—A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological entities. Exposure can be expressed as co-occurrence or contact, depending on the stressor and ecological component involved.

Community—An assemblage of populations of different species within a specified location in space and time.

Comparative risk assessment—A process that generally uses an expert judgment approach to evaluate the relative magnitude of effects and set priorities among a wide range of environmental problems (e.g., U.S. EPA, 1993b). Some applications of this process are similar to the problem formulation portion of an ecological risk assessment in that the outcome may help select topics for further evaluation and help focus limited resources on areas having the greatest risk reduction potential. In other situations, a comparative risk assessment is conducted more like a preliminary risk assessment. For example, EPA's Science Advisory Board used expert judgment and an ecological risk assessment approach to analyze future ecological risk scenarios and risk management alternatives (U.S. EPA, 1995a).

Conceptual model—The conceptual model describes a series of working hypotheses of how the stressor might affect ecological entities. The conceptual model also describes the ecosystem potentially at risk, the relationship between measures of effect and assessment endpoints, and exposure scenarios.

Cumulative distribution function (CDF)—Cumulative distribution functions are particularly useful for describing the likelihood that a variable will fall within different ranges of x. F(x) (i.e., the value of y at x in a CDF plot) is the probability that a variable will have a value less than or equal to x (figure B–1).

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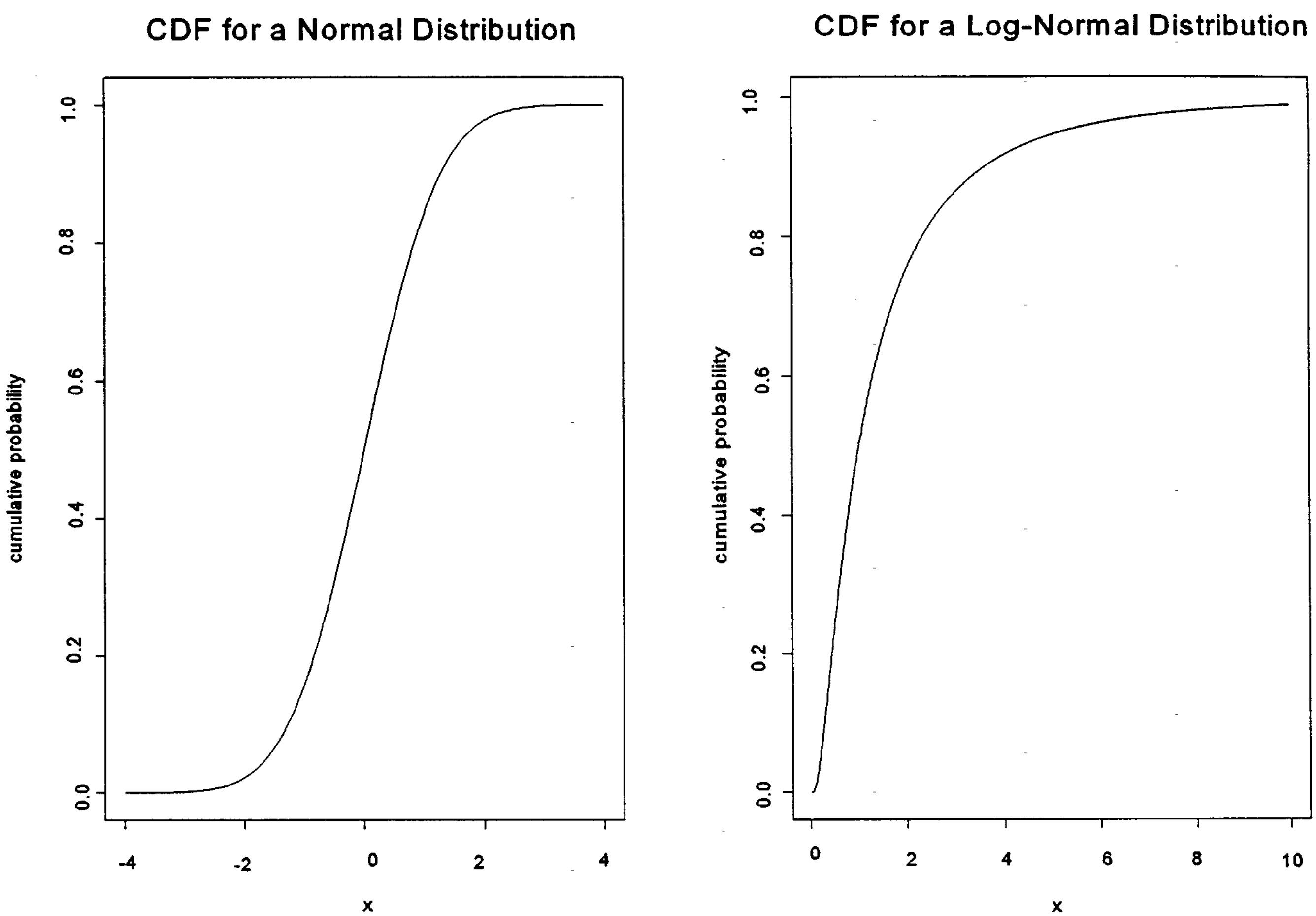

Figure B-1. Plots of Cumulative Distribution Function (CDF)

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Cumulative ecological risk assessment—A process that involves consideration of ‘‘the aggregate ecologic risk to the target entity caused by the accumulation of risk from multiple stressors’’ (Bender, 1996).

Disturbance—Any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment (modified from White and Pickett, 1985).

Ecological entity—A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity can be one component of an assessment endpoint.

Ecological risk assessment—The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

Ecosystem—The biotic community and abiotic environment within a specified location in space and time.

Environmental impact statement—Assessments are required under the National Environmental Policy Act (NEPA) to fully evaluate environmental effects associated with proposed major Federal actions. Like ecological risk assessments, environmental impact statements (EIS) typically require a ‘‘scoping process’’ analogous to problem formulation, an analysis by multidisciplinary teams, and a presentation of uncertainties (CEQ, 1986, cited in Suter, 1993a). By virtue of special expertise, EPA may cooperate with other agencies by preparing EISs or otherwise participating in the NEPA process.

Exposure—The contact or co-occurrence of a stressor with a receptor.

Exposure profile—The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model.

Exposure scenario—A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

Hazard assessment—This term has been used to mean either (1) evaluating the intrinsic effects of a stressor (U.S. EPA, 1979) or (2) defining a margin of safety or quotient by comparing a toxicologic effects concentration with an exposure estimate (SETAC, 1987).

Lines of evidence—Information derived from different sources or by different techniques that can be used to interpret and compare risk estimates. While this term is similar to the term ‘‘weight of evidence,’’ it does not necessarily imply assignment of quantitative weightings to information.

Lowest observed adverse effect level (LOAEL)—The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls.

Maximum acceptable toxic concentration (MATC)—For a particular ecological effects test, this term is used to mean either the range between the NOAEL and the LOAEL or the geometric mean of the NOAEL and the LOAEL for a particular test. The geometric mean is also known as the chronic value.

Measure of ecosystem and receptor characteristics—A measurable characteristic of the ecosystem or receptor that is used in support of exposure or effects analysis.

Measure of effect—A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint.

Measure of exposure—A measurable stressor characteristic that is used to help quantify exposure.

Measurement endpoint—See ‘‘measure of effect.’’

Median lethal concentration (LC_{50})—A statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions (ASTM, 1990).

No observed adverse effect level (NOAEL)—The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

Population—An aggregate of individuals of a species within a specified location in space and time.

Primary effect—An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect; compare with definition for secondary effect).

Probability density function (PDF)—Probability density functions are particularly useful in describing the relative likelihood that a variable will have different particular values of x. The probability that a variable will have a value within a small interval around x can be approximated by multiplying f(x) (i.e., the value of y at x in a PDF plot) by the width of the interval (figure B–2).

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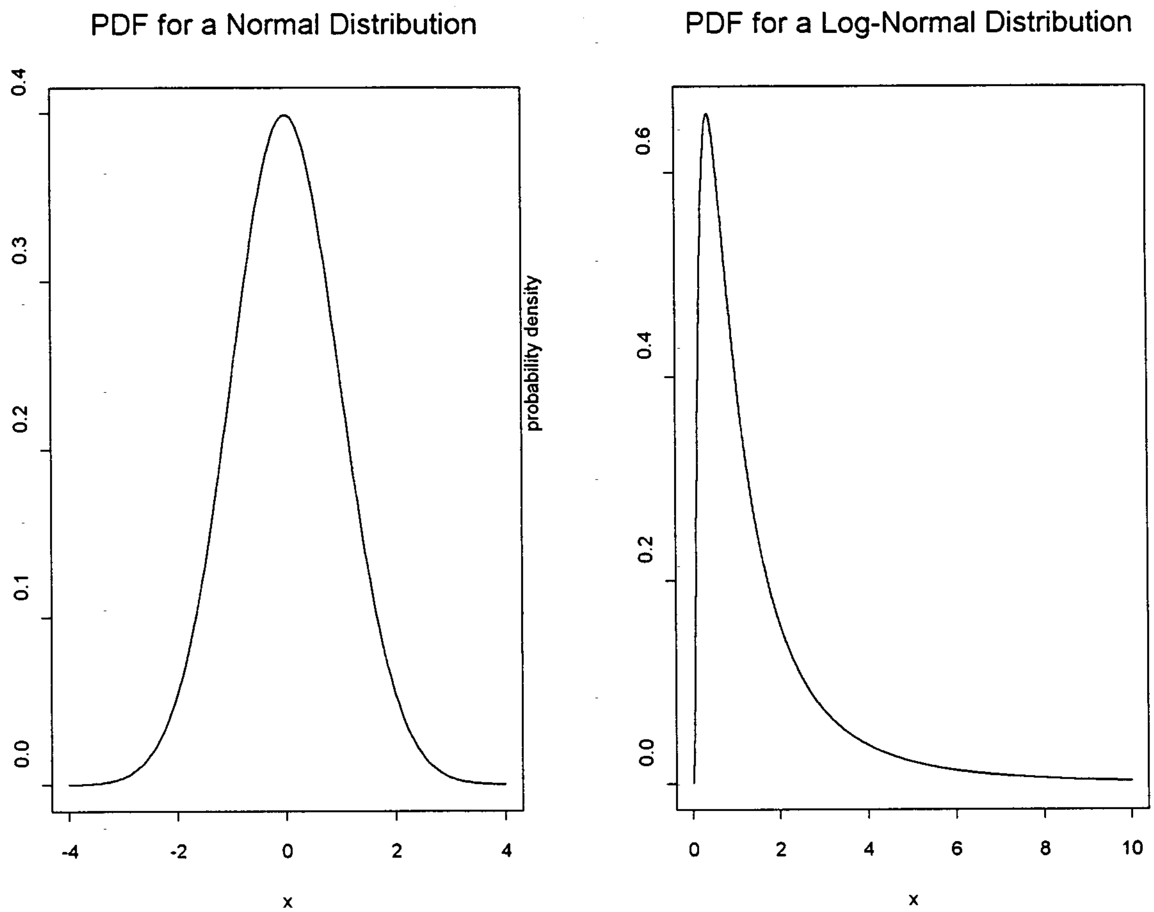

Figure B-2. Plots of Probability Density Functions (PDF)

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Receptor—The ecological entity exposed to the stressor.

Recovery—The rate and extent of return of a population or community to a condition that existed before the introduction of a stressor. Due to the dynamic nature of ecological systems, the attributes of a ''recovered'' system must be carefully defined.

Relative risk assessment—A process similar to comparative risk assessment. It involves estimating the risks associated with different stressors or management actions. To some, relative risk connotes the use of quantitative risk techniques, while comparative risk approaches more often rely on expert judgment. Others do not make this distinction.

Risk characterization—A phase of ecological risk assessment that integrates the exposure and stressor response profiles to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The adversity of effects is discussed, including consideration of the nature and intensity of the effects, the spatial and temporal scales, and the potential for recovery.

Secondary effect—An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects; compare with definition for primary effect).

Source—An entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors.

Source term—As applied to chemical stressors, the type, magnitude, and patterns of chemical(s) released.

Stress regime—The term stress regime has been used in at least three distinct ways: (1) to characterize exposure to multiple chemicals or to both chemical and nonchemical stressors (more clearly described as multiple exposure, complex exposure, or exposure to mixtures), (2) as a synonym for exposure that is intended to avoid overemphasis on chemical exposures, and (3) to describe the series of interactions of exposures and effects resulting in secondary exposures, secondary effects, and, finally, ultimate effects (also known as risk cascade [Lipton et al., 1993]) or causal chain, pathway, or network (Andrewartha and Birch, 1984).

Stressor—Any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent).

Stressor-response profile—The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

Trophic levels—A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial green plants comprise the first trophic level and herbivores comprise the second).

Appendix C.—Conceptual Model Examples

Conceptual model diagrams are visual representations of the conceptual models. They may be based on theory and logic, empirical data, mathematical models, and probability models. These diagrams are useful tools for communicating important pathways in a clear and concise way. They can be used to ask new questions about relationships that help generate plausible risk hypotheses. Further discussion of conceptual models is found in section 3–4.

Flow diagrams like those shown in figures C–1 through C–3 are typical conceptual model diagrams. When constructing flow diagrams like these, it is helpful to use distinct and consistent shapes to distinguish among stressors, assessment endpoints, responses, exposure routes, and ecosystem processes. Although flow diagrams are often used to illustrate conceptual models, there is no set configuration for conceptual model diagrams. Pictorial representations of the processes of an ecosystem can be more effective (e.g., Bradley and Smith, 1989).

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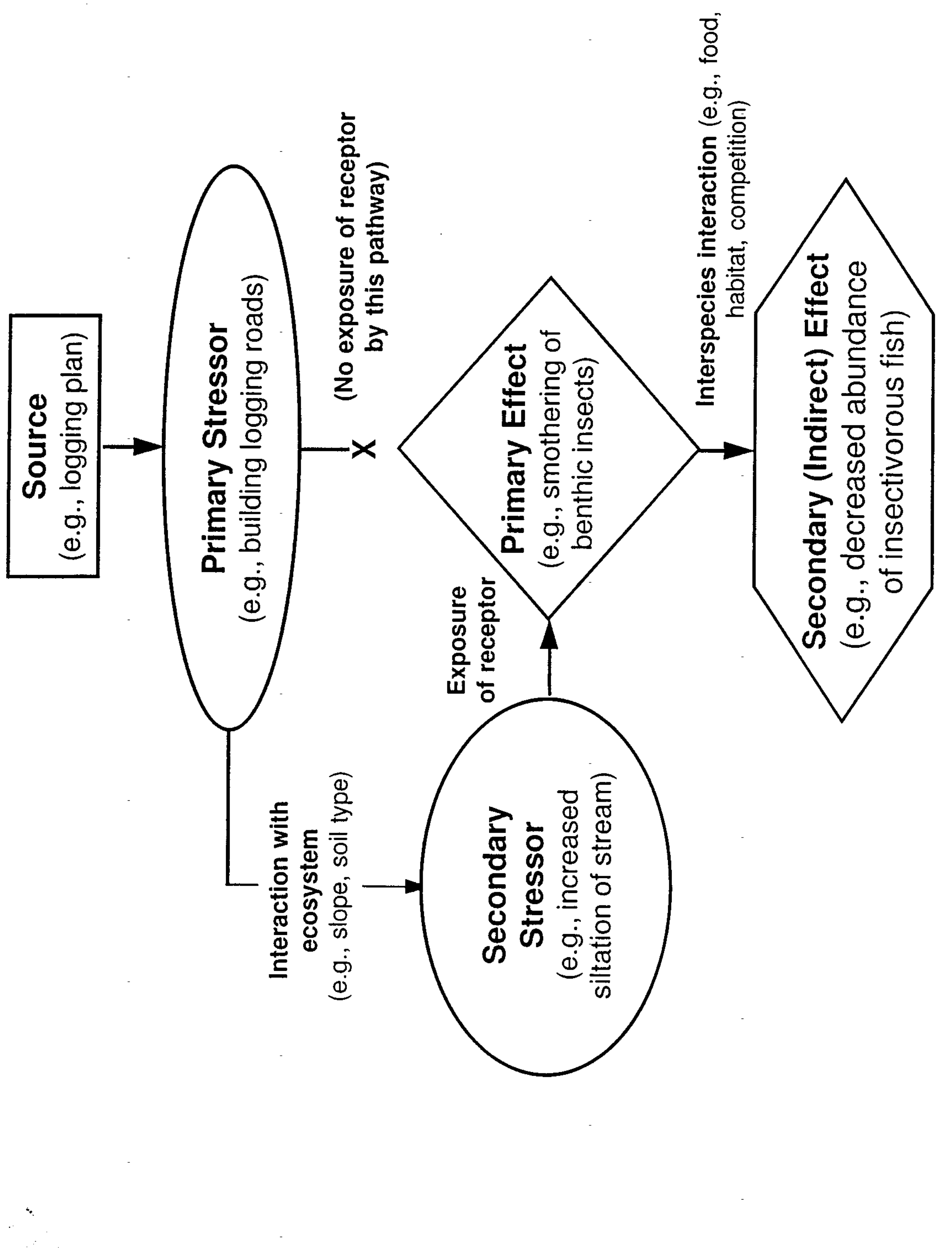

Figure C-1. Conceptual model for logging.

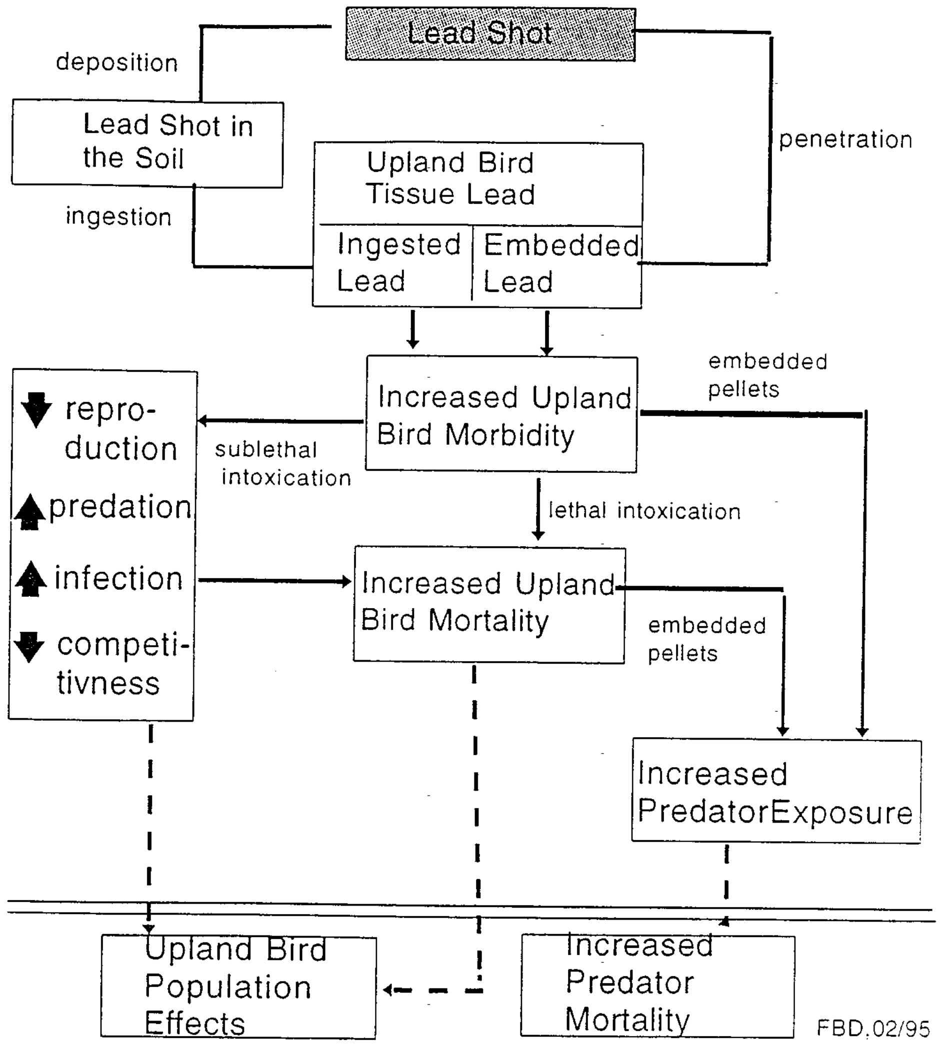

Figure C-2. Conceptual model for tracking stress associated with lead shot through upland ecosystems. Reprinted from *Environmental Toxicology and Chemistry* by Kendall et al. (1996) with permission of the Society of Environmental Toxicology and Chemistry (copyright 1996).

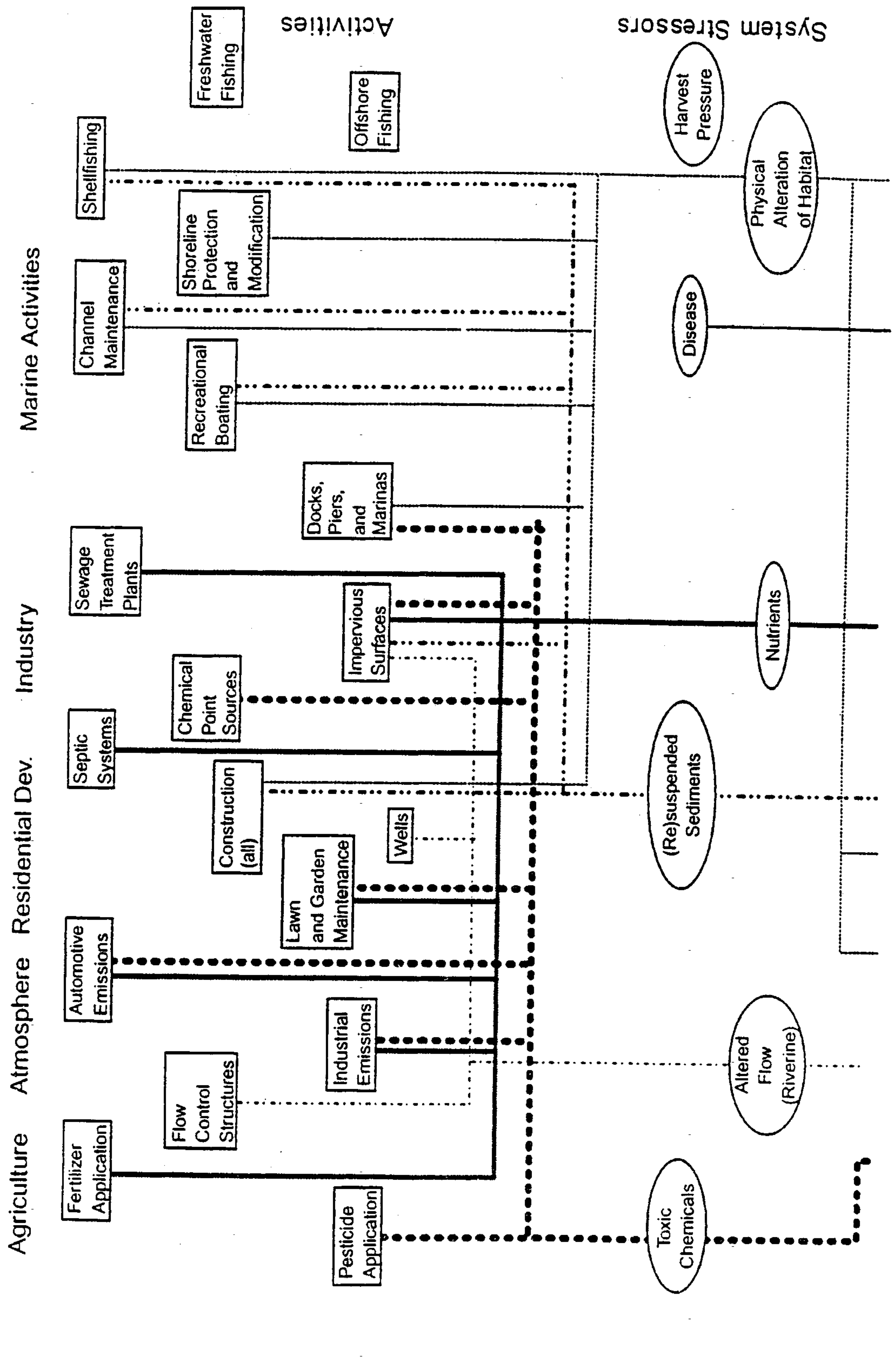

Figure C-3. Waquoit Bay watershed conceptual model.

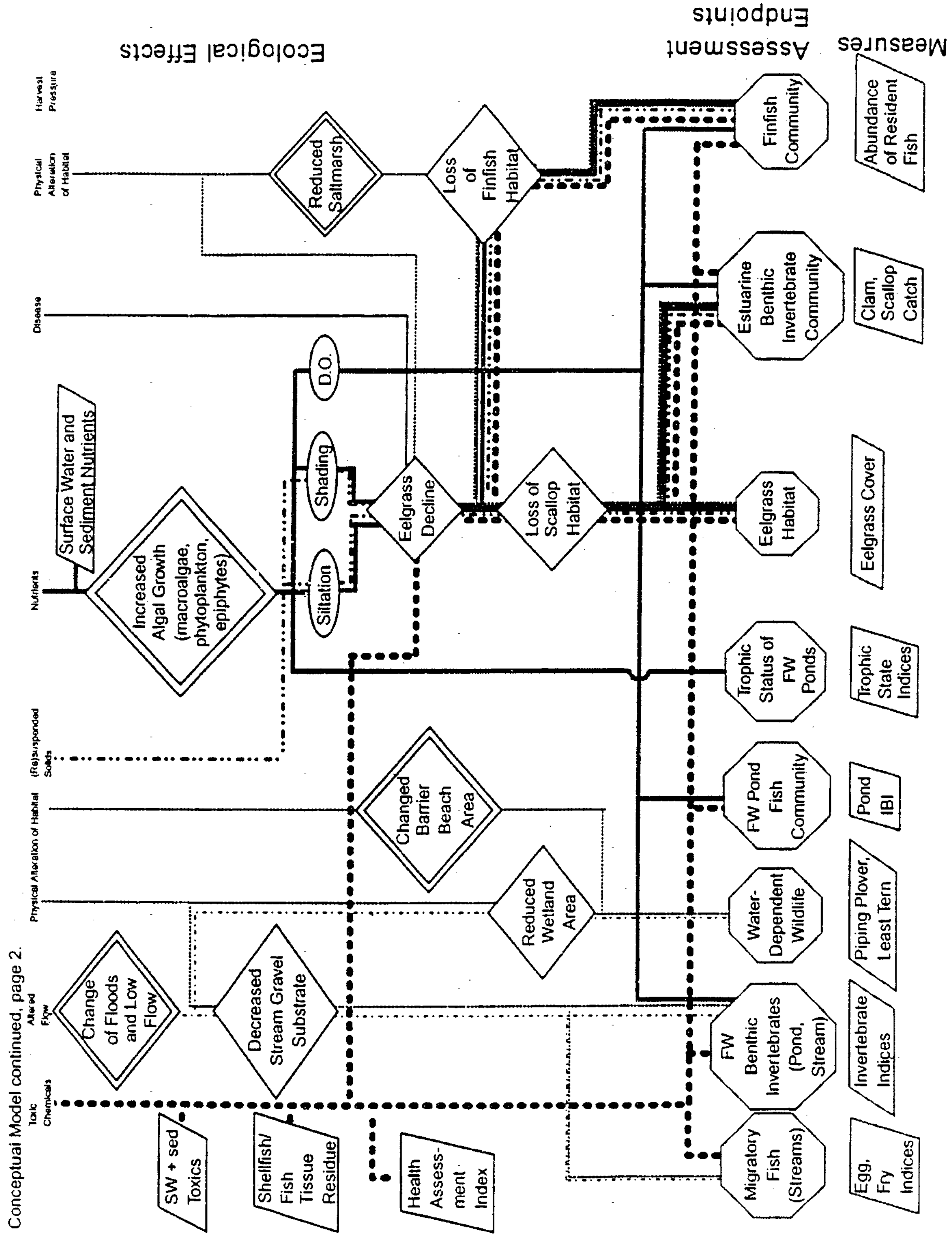

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Figure C–1 illustrates the relationship between a primary physical stressor (logging roads) and an effect on an assessment endpoint (fecundity in insectivorous fish). This simple diagram illustrates that building logging roads (which could be considered a stressor or a source) in ecosystems where slope, soil type, low riparian cover, and other ecosystem characteristics lead to the erosion of soil, which enters streams and smothers the benthic organisms (exposure pathway is not explicit in this diagram). Because of the dependence of insectivorous fish on benthic organisms, the fish are believed to be at risk from the building of logging roads. Each arrow in this diagram represents a hypothesis about the proposed relationship (e.g., human action and stressor, stressor and effect, primary effect to secondary effect). Each risk hypothesis provides insights into the kinds of data that will be needed to verify that the hypothesized relationships are valid.

Figure C–2 is a conceptual model used by Kendall et al. (1996) to track a contaminant through upland ecosystems. In this example, upland birds are exposed to lead shot when it becomes embedded in their tissue after being shot and by ingesting lead accidentally when feeding on the ground. Both are hypothesized to result in increased morbidity (e.g., lower reproduction and competitiveness and higher predation and infection) and mortality, either directly (lethal intoxication) or indirectly (effects of morbidity leading to mortality). These effects are believed to result in changes in upland bird populations and, due to hypothesized exposure of predators to lead, to increase predator mortality. This example shows multiple exposure pathways for effects on two assessment endpoints. Each arrow contains within it assumptions and hypotheses about the relationship depicted that provide the basis for identifying data needs and analyses.

Figure C–3 is a conceptual model adapted from the Waquoit Bay watershed risk assessment. At the top of the model, multiple human activities that occur in the watershed are shown in rectangles. Those sources of stressors are linked to stressor types depicted in ovals. Multiple sources are shown to contribute to an individual stressor, and each source may contribute to more than one stressor. The stressors then lead to multiple ecological effects depicted again in rectangles. Some rectangles are double-lined to indicate effects that can be directly measured for data analysis. Finally, the effects are linked to particular assessment endpoints. The connections show that one effect can result in changes in many assessment endpoints. To fully depict exposure pathways and types of effects, specific portions of this conceptual model would need to be expanded to illustrate those relationships.

Appendix D.—Analysis Phase Examples

The analysis phase process is illustrated here for a chemical, physical, and biological stressor. These examples do not represent all possible approaches but illustrate the analysis phase process using information from actual assessments.

D.1. Special Review of Granular Formulations of Carbofuran Based on Adverse Effects on Birds

Figure D–1 is based on an assessment of the risks of carbofuran to birds under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Houseknecht, 1993). Carbofuran is a broad-spectrum insecticide and nematicide applied primarily in granular form on 27 crops as well as forests and pineseed orchards. The assessment endpoint was survival of birds that forage in agricultural areas where carbofuran is applied.

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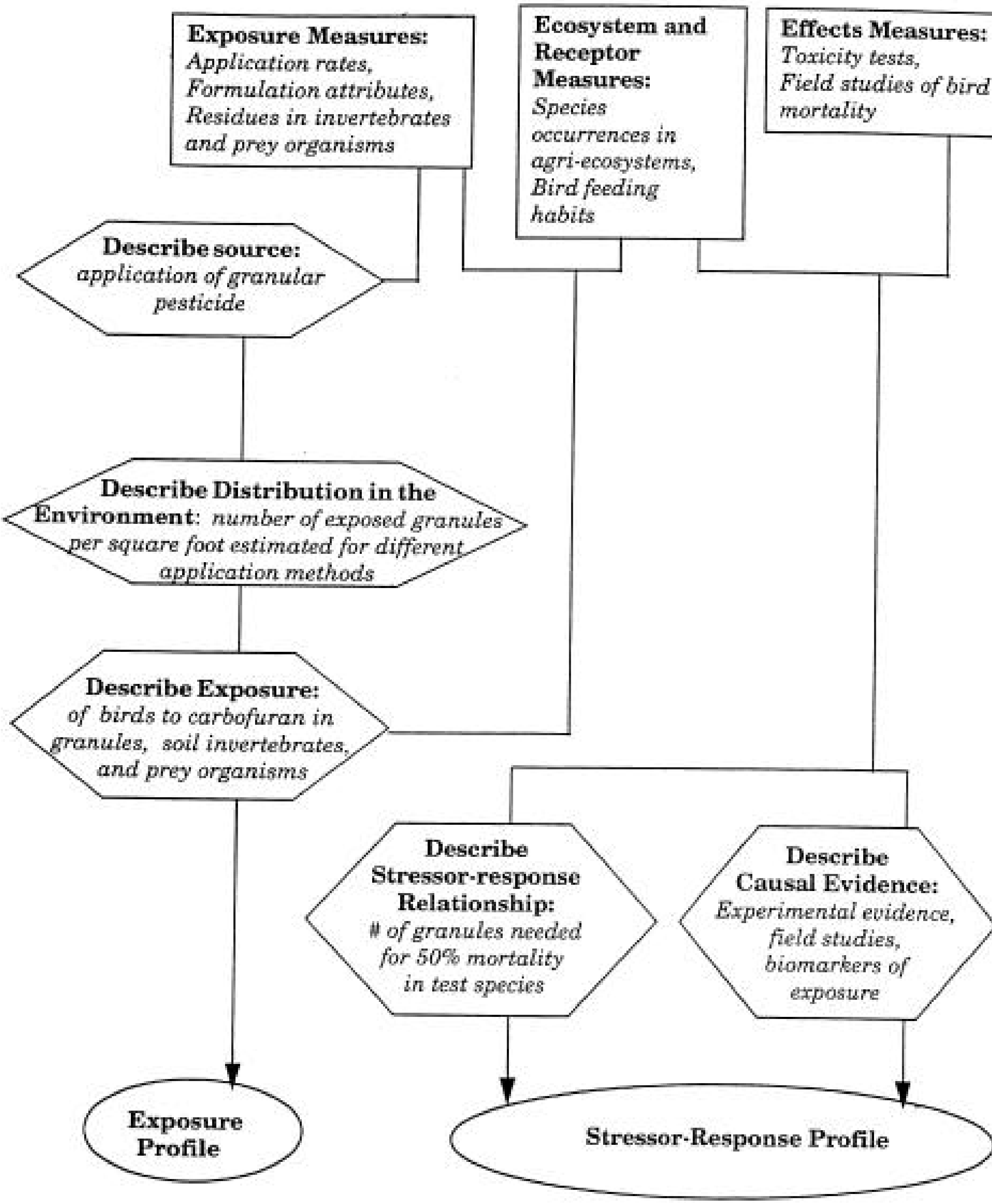

Figure D-1. Example of the analysis phase process: special review of carbofuran. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase focused on birds that may incidentally ingest granules as they forage or that may eat other animals that contain granules or residues. Measures of exposure included application rates, attributes of the formulation (e.g., size of granules), and residues in prey organisms. Measures of the ecosystem and receptors included an inventory of bird species that may be exposed following applications for 10 crops. The birds' respective feeding behaviors were considered in developing routes of exposure. Measures of effect included laboratory toxicity studies and field investigations of bird mortality.

The source of the chemical was application of the pesticide in granular form. The distribution of the pesticide in agricultural fields was estimated based on the application rate. The number of exposed granules was estimated from literature data. Based on a review of avian feeding behavior, seed-eating birds were assumed to ingest any granules left uncovered in the field. The intensity of exposure was summarized as the number of exposed granules per square foot.

The stressor-response relationship was described using the results of toxicity tests. These data were used to construct a toxicity statistic expressed as the number of granules needed to kill 50% of the test birds (i.e., granules per LD_{50}), assuming 0.6 mg of active ingredient (AI) per granule and average body weights for the birds tested. Field studies were used to document the occurrence of bird deaths following applications and provide further causal evidence. Carbofuran residues and cholinesterase levels were used to confirm that exposure to carbofuran caused the deaths.

D.2. Modeling Losses of Bottomland-Forest Wetlands

Figure D–2 is based on an assessment of the ecological consequences (risks) of long-term changes in hydrologic conditions (water-level elevations) for three habitat types in the Lake Verret Basin of Louisiana (Brody et al., 1989, 1993; Connor and Brody, 1989). The project was intended to provide a habitat-based approach for assessing the environmental impacts of Federal water projects under the National Environmental Policy Act and Section 404 of the Clean Water Act. Output from the models provided risk managers with information on how changes in water elevation might alter the ecosystem. The primary anthropogenic stressor addressed in this assessment was artificial levee construction for flood control, which contributes to land subsidence by reducing sediment deposition in the floodplain. Assessment endpoints included forest community structure and habitat value to wildlife species and the species composition of the wildlife community.

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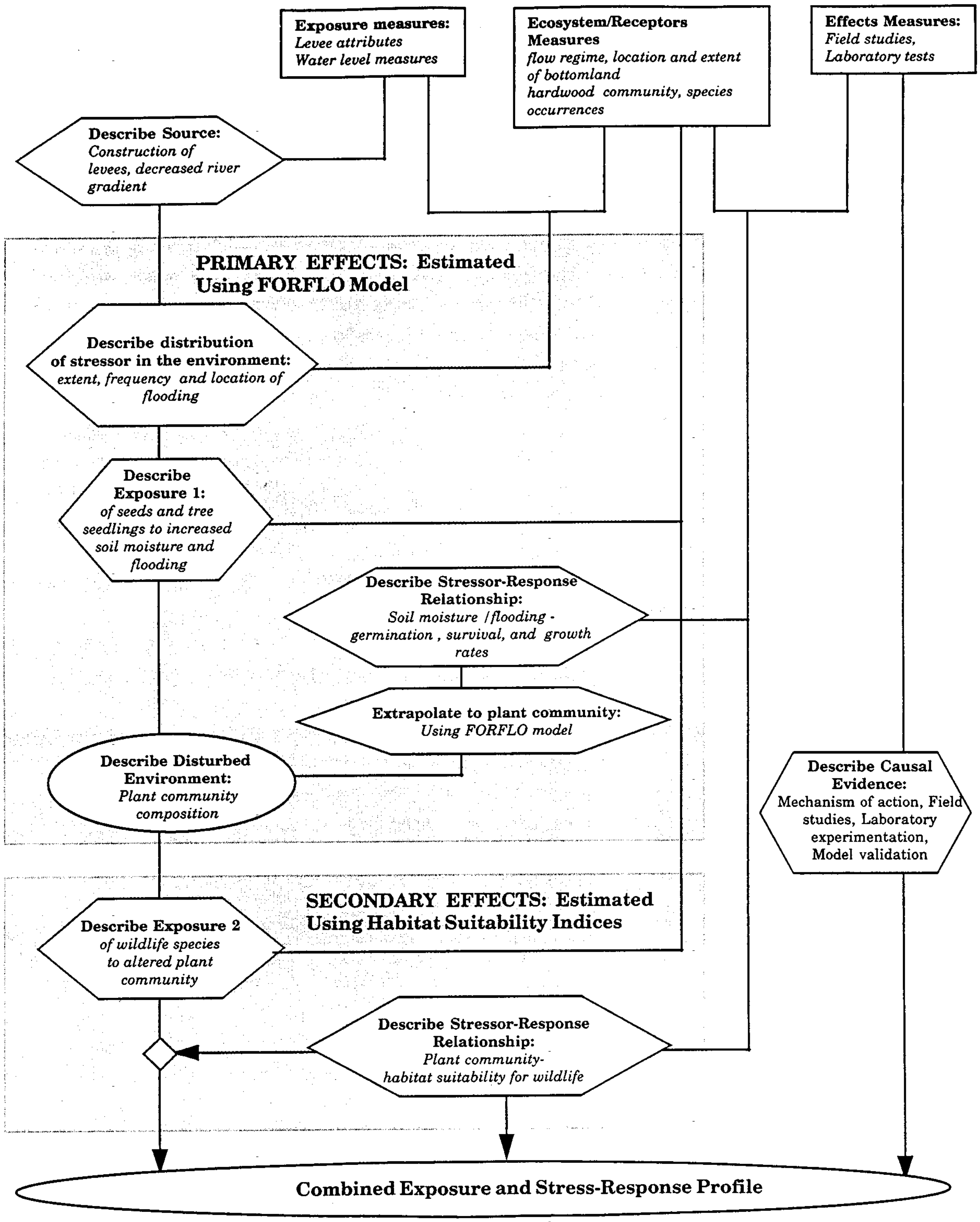

Figure D-2. Example of the analysis phase process: modeling losses of bottomland hardwoods. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase began by considering primary (direct) effects of water-level changes on plant community composition and habitat characteristics. Measures of exposure included the attributes and placement of the levees and water-level measurements. Ecosystem and receptor measures included location and extent of bottomland-hardwood communities, plant species occurrences within these communities, and information on the historic flow regimes. Effects measures included laboratory studies of plant response to moisture and field measurements along moisture gradients.

While the principal stressor under evaluation was the construction of levees, the decreased gradient of the river due to sediment deposition at its mouth also contributed to increased water levels. The extent and frequency of flooding were simulated by the FORFLO model based on estimates of net subsidence rates from levee construction and decreased river gradient. Seeds and seedlings of the tree species were assumed to be exposed to the altered flooding regime. Stressor-response relationships describing plant response to moisture (e.g., seed germination, survival) were embedded within the FORFLO model. This information was used by the model to simulate changes in plant communities: The model tracks the species type, diameter, and age of each tree on simulated plots from the time the tree enters the plot as a seedling or sprout until it dies. The FORFLO model calculated changes in the plant community over time (from 50 to 280 years). The spatial extent of the three habitat types of interest—wet bottomland hardwoods, dry bottomland hardwoods, and cypress-tupelo swamp—was mapped onto a Geographic Information System (GIS) along with the hydrological information. Then the changes projected by FORFLO were manually linked to the GIS to show how the spatial distribution of different communities would change. Evidence that flooding would actually cause these changes included comparisons of model predictions with field measurements, the laboratory studies of plant response to moisture, and knowledge of the mechanisms by which flooding elicits changes in plant communities.

Secondary (indirect) effects on wildlife associated with changes in the habitat provided by the plant community formed the second part of the analysis phase. Important measures included life-history characteristics and habitat needs of the wildlife species. Effects on wildlife were inferred by evaluating the suitability of the plant community as habitat. Specific aspects of the community structures calculated by the FORFLO model provided the input to this part of the analysis. For example, the number of snags was used to evaluate habitat value for woodpeckers. Resident wildlife (represented by five species) were assumed to co-occur with the altered plant community. Habitat value was evaluated by calculating the Habitat Suitability Index (HSI) for each habitat type multiplied by the habitat type's area.

A combined exposure and stressor-response profile is shown in figure D–2; these two elements were combined with the models used for the analysis and then used directly in risk characterization.

D.3. Pest Risk Assessment of Importation of Logs From Chile

Figure D–3 is based on the assessment of potential risks to U.S. forests due to the incidental introduction of insects, fungi, and other pests inhabiting logs harvested in Chile and transported to U.S. ports (USDA, 1993). This risk assessment was used to determine whether actions to restrict or regulate the importation of Chilean logs were needed to protect U.S. forests and was conducted by a team of six experts under the auspices of the U.S. Department of Agriculture Forest Service. Stressors include insects, forest pathogens (e.g., fungi), and other pests. The assessment endpoint was the survival and growth of tree species (particularly conifers) in the western United States. Damage that would affect the commercial value of the trees as lumber was clearly of interest.

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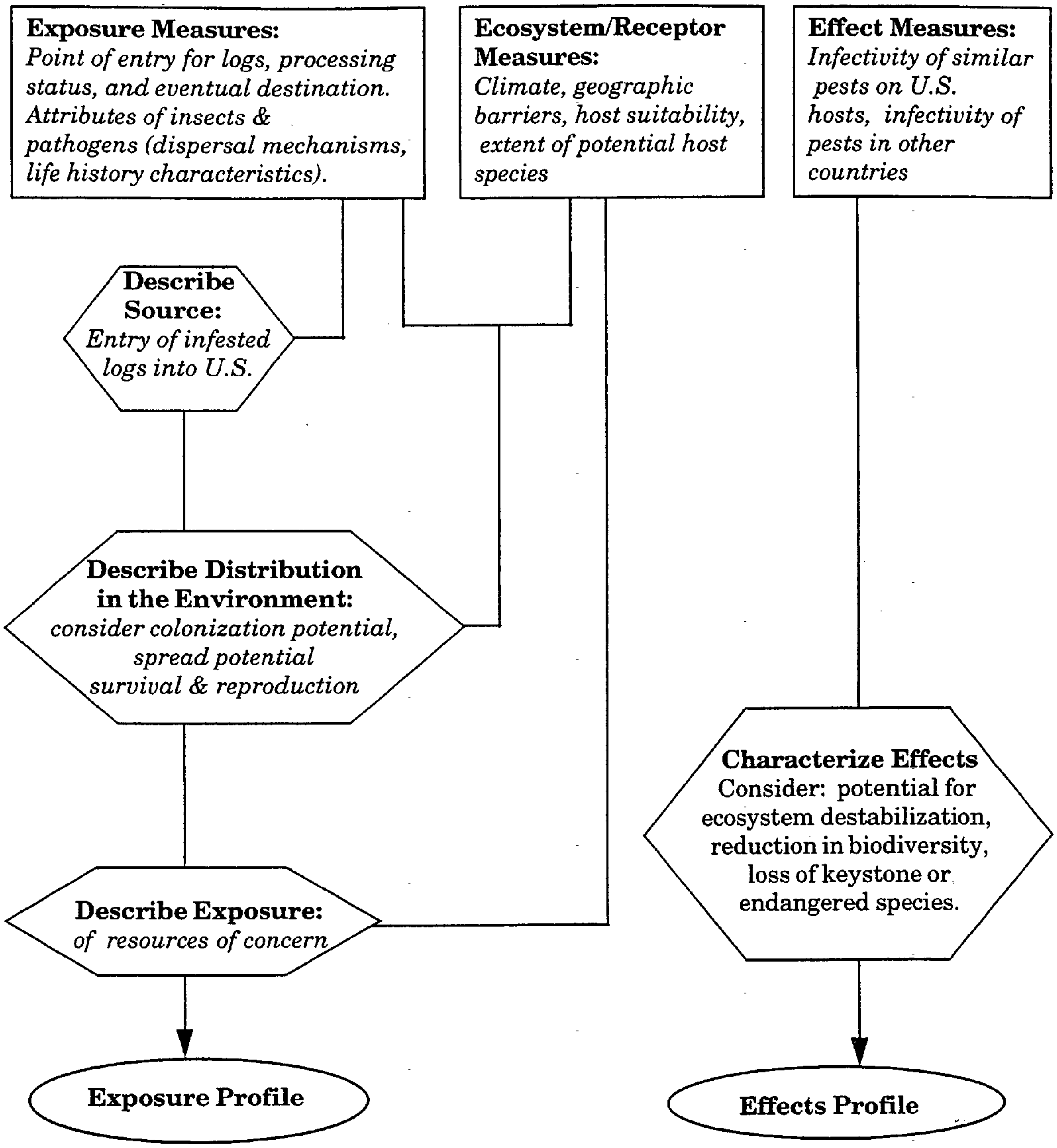

Figure D-3. Example of the analysis phase process: pest risk assessment of the importation of logs from Chile. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase was carried out by eliciting professional opinions from a team of experts. Exposure measures used by the team included distribution information for the imported logs and attributes of the insects and pathogens such as dispersal mechanisms and life history characteristics. Ecosystem and receptor measures included the climate of the United States, location of geographic barriers, knowledge of host suitability, and ranges of potential host species. Effect measures included knowledge of the infectivity of these pests in other countries and the infectivity of similar pests on U.S. hosts.

This information was used by the risk assessment team to evaluate the potential for exposure. They began by evaluating the likelihood of entry of infested logs into the United States. The distribution of the organisms given entry was evaluated by considering the potential for colonization and spread beyond the point of entry as well as the likelihood of organisms surviving and reproducing. The potential for exposure was summarized by assigning each of the above elements a judgment-based value of high, medium, or low.

The evaluation of ecological effects was also conducted based on collective professional judgment. Of greatest relevance to this guidance was the consideration of environmental damage potential, defined as the likelihood of ecosystem destabilization, reduction in biodiversity, loss of keystone species, and reduction or elimination of endangered or threatened species. (The team also considered economic damage potential and social and political influences; however, these guidelines consider those factors to be part of the risk management process.) Again, each consideration was assigned a value of high, medium, or low to summarize the potential for ecological effects.

Appendix E.—Criteria for Determining Ecological Adversity: A Hypothetical Example (Adapted from Harwell et al., 1994)

As a result of a collision at sea, an oil tanker releases 15 million barrels of #2 fuel oil 3 km offshore. It is predicted that prevailing winds will carry the fuel onshore within 48 to 72 hours. The coastline has numerous small embayments that support an extensive shallow, sloping subtidal community and a rich intertidal community. A preliminary assessment determined that if no action were taken, significant risks to the communities would result. Additional risk assessments were conducted to determine which of two options should be used to clean up the oil spill.

Option 1 is to use a dispersant to break up the slick, which would reduce the likelihood of extensive onshore contamination but would cause extensive mortality to the phytoplankton, zooplankton, and ichthyoplankton, which are important for commercial fisheries. Option 2 is to try to contain and pump off as much oil as possible; this option anticipates that a shift in wind direction will move the spill away from shore and allow for natural dispersal at sea. If this does not happen, the oil will contaminate the extensive sub- and intertidal mud flats, rocky intertidal communities, and beaches and pose an additional hazard to avian and mammalian fauna. It is assumed there will be a demonstrable change beyond natural variability in the assessment endpoints (e.g., structure of planktonic, benthic, and intertidal communities). What is the adversity of each option?

- Nature and severity of the effect. For both options, the magnitude of change in the assessment endpoints is likely to be severe. Planktonic populations often are characterized by extensive spatial and temporal variability. Nevertheless, within the spatial boundaries of the spill, the use of dispersants is likely to produce complete mortality of all planktonic forms within the upper 3 m of water. For benthic and intertidal communities that generally are stable and have less spatial and temporal variability than planktonic forms, oil contamination will likely result in severe impacts on survival and chronic effects lasting for several years. Thus, under both options, changes in the assessment endpoints will probably exceed the natural variability for threatened communities in both space and time.
- Spatial scale. The areal extent of impacts is similar for each of the options. While extensive, the area of impact constitutes a small percentage of the landscape. This leaves considerable area available for replacement stocks and creates significant fragmentation of either the planktonic or inter- and subtidal habitats. Ecological adversity is reduced because the area is not a mammalian or avian migratory corridor.
- Temporal scale and recovery. Based on experience with other oil spills, it is assumed that the effects are reversible over some time period. The time needed for reversibility of changes in phytoplankton and zooplankton populations should be short (days to weeks) given their rapid generation times and easy immigration from adjacent water masses. Similarly, although ichthyoplankton do not reproduce, they typically experience extensive natural mortality, and immigration is readily available from surrounding water masses. On the other hand, the time needed for reversibility of changes in benthic and intertidal communities is likely to be long (years to decades). First, the stressor (oil) would be likely to persist in sediments and on rocks for several months to years. Second, the life histories of the species comprising these communities span 3 to 5 years. Third, the reestablishment of benthic intertidal community and ecosystem structure (hierarchical composition and function) often requires decades.

Both options result in (1) assessment endpoint effects that are of great severity, (2) exceedances of natural variability for those endpoints, and (3) similar estimates of areal impact. What distinguishes the two options is temporal scale and reversibility. In this regard, changes to the benthic and intertidal ecosystems are considerably more adverse than those to the plankton. On this basis, the option of choice would be to disperse the oil, effectively preventing it from reaching shore where it would contaminate the benthic and intertidal communities.

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